

No. 24-1365

**In the United States Court of Appeals
for the District of Columbia Circuit**

DOCTORS FOR DRUG POLICY REFORM; BRYON ADINOFF, DR.,

Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL
CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT
ADMINISTRATION,

Respondents

On Petition for Review of Orders of the Drug Enforcement Administration
(Oct. 28, 2024 and Nov. 25, 2024)

**PETITIONERS' APPENDIX
VOLUME 4 OF 6
App.959 to App.1379**

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Dated: February 17, 2025

Respectfully submitted,

/s/Austin T. Brumbaugh

Austin T. Brumbaugh

D.C. Circuit Bar No. 65727

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Attorney for Petitioners



[EXTERNAL] Docket No. DEA-1362 (Schedules of Controlled Substances: Rescheduling of Marijuana NPRM)

From Gordon, Stephen <Sgordon@aar.org>

Date Mon 9/30/2024 1:37 PM

To NPRM <NPRM@dea.gov>

Cc Moller, Jeff <JMoller@aar.org>

The Association of American Railroads (AAR) would like the opportunity to participate in the hearing scheduled for December 2, 2024, at 9 a.m. ET in Arlington, VA.

As background, AAR is a trade association whose membership includes freight railroads that operate 83% of the line-haul mileage, employ 95% of the workers, and account for 97% of the freight revenues of all railroads in the United States; and passenger railroads that operate intercity passenger trains and provide commuter rail service.

AAR submitted joint comments on the rulemaking with the American Short Line and Regional Railroad Association highlighting the potential impact of rescheduling on existing railroad industry drug and alcohol testing programs, which include certain mandated testing pursuant to U.S. DOT regulations. AAR also joined a wider coalition comment of twenty transportation industry groups stressing the need for DEA to consider the impacts of the proposed rescheduling on the safety of the U.S. transportation system.

Thank you,
Stephen Gordon

Stephen Gordon

Associate General Counsel for Safety
Association of American Railroads
425 Third Street, SW
Washington, DC 20024
Office: 202-639-2504
Cell: 202-577-1027



Khurshid Khoja
Principal

Greenbridge Corporate Counsel, P.C.
500 Capitol Mall
Suite 2350
Sacramento, CA 95814
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September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, VA 22152
nprm@dea.gov

Subject: Notice of Appearance by BayMedica, LLC (Docket No. DEA-1362)

Dear Administrator:

Please take notice that my client BayMedica, LLC, a Delaware limited liability company ("BayMedica") will appear in the matter of the Drug Enforcement Administration's Proposed Rule on the Rescheduling of Marijuana, Docket No. DEA-1362 (the "Proposed Rule") and intends to participate in the December 2, 2024 hearing. This notice of appearance ("Notice") is intended to satisfy the requirements of 21 CFR § 1308.44 and 21 CFR § 1316.48; as such, Section (A) of this Notice "state[s] with particularity" BayMedica's "interest ... in the proceeding," Section (B) "state[s] with particularity the objections or issues ... concerning which [it] desires to be heard," and Section (C) briefly states BayMedica's "position ... with regard to the particular objections or issues," and includes descriptions of relevant evidence on material issues of fact and expert opinion that BayMedica intends to present during the hearing per 21 CFR § 1308.42.

(A) BayMedica's Interest in the Proceeding

BayMedica is an "interested person" as defined in 21 CFR 1300.01(b), as it would be "adversely affected or aggrieved by" the Proposed Rule. BayMedica is in the business of meeting consumer demand for certain naturally-occurring, non-intoxicating and currently unscheduled rare and minor cannabinoids (sought after for potential wellness benefits). It does so by supplying cost-effective bioidentical synthetic equivalents of these non-intoxicating cannabinoids through its proprietary production methods and its distribution to lawful manufacturers of hemp and marijuana products ("Non-Intoxicating Cannabinoids").¹ For the fiscal year that ended June 30, 2024, BayMedica's business earned approximately \$4.6 million.²

BayMedica easily satisfies the requirements for being "adversely affected or aggrieved by" the Proposed Rule because the revised definition of "Tetrahydrocannabinol" under 21 CFR § 1308.11 contained within the Proposed Rule (the "Proposed Definition") could make some or all of their business federally illegal.³ As discussed throughout this Notice, BayMedica can credibly allege that it would suffer substantial economic injury if the Proposed Definition were to become final as currently drafted,⁴ and that "that interpretations of the [Proposed



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Definition's] provisions or scope could directly affect them."⁵ To the extent the Proposed Definition could also contravene the scheduling procedures set forth in Controlled Substances Act ("CSA") at 21 USC §811(a) and 21 USC §811(e), BayMedica also has standing under Section 10(a) of the federal Administrative Procedure Act.⁶

(B) BayMedica Desires to be Heard on the DEA's New Definition for "Tetrahydrocannabinol" under the Proposed Rule

As explained below, BayMedica desires to be heard on the DEA's proposed definition of "Tetrahydrocannabinol" under 21 CFR § 1308.11 offered in the Proposed Rule:

(30) Tetrahydrocannabinols—7370

(i) Meaning tetrahydrocannabinols, except as in paragraphs (d)(30)(ii) and (iii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extracts of such plant, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.

(ii) Tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.

(iii) Tetrahydrocannabinols do not include any substance that falls within the definition of marijuana set forth in 21 U.S.C. 802(16).

BayMedica objects to the adoption of the Proposed Definition, as it could permit the DEA to deem currently unscheduled Non-Intoxicating Cannabinoids to be (as a matter of law) Schedule I *tetrahydrocannabinols* (including, but not limited to, therapeutically beneficial and Non-Intoxicating Cannabinoids such as CBC, THCV and THCA).

(1) The DEA's Revisions in the Proposed Definition Create Ambiguity

The Proposed Definition creates unnecessary ambiguity and confusion as drafted, and it could potentially cause currently unscheduled Non-Intoxicating Cannabinoids to be designated as prohibited Schedule I controlled substances without any formal scheduling action or order as required under the CSA at 21 USC §811(a) and 21 USC §811(e) respectively. To convey the full extent of this issue, it's useful to isolate the DEA's proposed revisions to the current existing definition of Tetrahydrocannabinols:



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(~~31~~30) Tetrahydrocannabinols

(i) Meaning tetrahydrocannabinols, except as in ~~paragraph~~paragraphs (d)(~~31~~30)(ii) and (iii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous ~~extractives~~extracts of such plant, ~~and/or~~ synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, ~~such as the following:-~~

~~1-cis or trans-tetrahydrocannabinol, and their optical isomers~~

~~6-cis or trans-tetrahydrocannabinol, and their optical isomers~~

~~3, 4-cis or trans-tetrahydrocannabinol, and its optical isomers~~

~~(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)~~

(ii) Tetrahydrocannabinols ~~does~~do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.

(iii) Tetrahydrocannabinols do not include any substance that falls within the definition of marijuana set forth in 21 U.S.C. 802(16).

Note that the carve-out for marijuana-derived THC included under new clause (iii) effectively eliminates the inclusion of any plant derived THC from the Proposed Definition when it is incorporated within clause (i) to modify "tetrahydrocannabinols ... naturally contained in a plant of the genus Cannabis (cannabis plant)." While this was intended to distinguish plant-derived THC from the synthetic forms of THC still classified under Schedule I, it also results in an unnecessarily confusing definition which leaves the reader wondering why the reference to plant-derived THC remains in clause (i).

Additionally, given that hundreds of new pharmacologically active "substances" have been discovered in the cannabis plant since the bulk of the current definition of THC was crafted in 1968 (when it was broadly assumed to be the only active substance in cannabis),⁷ it adds to the confusion of determining the full scope of what's meant today by the phrase, "synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extracts of such plant" or "synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant."



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It's also worth noting that while the phrase "*with similar chemical structure and pharmacological activity*" was in the DEA's original definition, that standard for inclusion of a synthetic cannabinoid under the rubric of tetrahydrocannabinol is seemingly *less strict* than what would be deemed a Schedule I "analogue" of THC, which require a "substantially similar" chemical structure or pharmacological effect to THC.⁸ This could lead to the inclusion of Non-Intoxicating Cannabinoids like THCV under the Proposed Definition, even though they may exhibit much less similarity to THC than other non-bioidentical synthetic cannabinoids recently scheduled by the DEA.⁹

Finally, the DEA's deletion of the 3 specific examples of THC isomers that constitutes a "tetrahydrocannabinol" also adds to the confusion and ambiguity of determining which cannabinoids fall under the Proposed Definition.

(2) DEA Pronouncements on other Non-Intoxicating Cannabinoids Add to the Confusion

BayMedica's concern is prompted not only by the DEA's construction of and revisions to the Proposed Definition, but also by the DEA's recent pronouncements on THCA. Taken at face value, these pronouncements suggest that the DEA may well apply the Proposed Definition to capture currently lawful Non-Intoxicating Cannabinoids, notwithstanding its longstanding practice (of formally scheduling (1) THC analogues under the Federal Analogues Act (2) synthetic cannabinoids with pharmacological effects that mimic THC under Section 811(a) of the CSA and (3) immediate precursors of other controlled substances under Section 811(a) of the CSA¹⁰) and the absence of any formal scheduling action with respect to those Non-Intoxicating Cannabinoids.

For example, in a recent letter from Terry Boos, Chief of the Drug & Chemical Evaluation Section of Diversion Control Division of the DEA, dated May 13, 2024,¹¹ Dr. Boos communicated the DEA's statutory interpretation of both 21 U.S.C. § 812, Schedule I(c)(17) of the CSA and Section 7 U.S.C. 1639o of the Agriculture Improvement Act of 2018, Public Law 115–334 (the "2018 Farm Bill"), concluding that "*cannabis-derived THCA does not meet the definition of [federally legal] hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9-THC,*" and "[t]he CSA classifies tetrahydrocannabinols (*such as THCA*) as controlled in schedule I" (emphasis added).

While it is absolutely true that THCA has the potential to convert to THC, this was already contemplated by Congress in its approach to defining "hemp". Just as the DEA and federal courts acknowledge that Congress did not intend the threshold defined for Delta-9 THC



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to apply to Delta-8 THC, Congress could not have intended for any guidelines adopted by the USDA to approximate the total potential Delta-9 THC content of pre-harvested hemp¹² to also be a proxy for newly designating THCA as a Schedule I controlled substance equivalent to THC.¹³ Congress was abundantly clear when it defined federally lawful hemp to include

"all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

As such, it serves no purpose for the DEA to attempt to classify THCA as "equivalent to THC" in contravention of Congress' intent in both the CSA and 2018 Farm Bill. As a matter of black letter law THCA is currently *not* a scheduled controlled substance unless it's specifically marijuana-derived. THCA ($C_{22}H_{30}O_4$) has a different chemical structure and molecular formula from THC ($C_{21}H_{30}O_2$), is *not* a "derivative" or "isomer" of THC (nor is it an analogue) and as a Non-Intoxicating Cannabinoid it does *not* display the same pharmacological activity as THC. Thus, as a different cannabinoid from THC, THCA would need to be scheduled before it could be legally deemed the functional equivalent of a Schedule I controlled substance. However, THCA has never been through formal scheduling by the DEA, as an examination of the Federal Register proves.¹⁴

Even as an immediate precursor of THC (per 21 USC §802(23)), THCA still can't be deemed a Schedule I-equivalent based solely on the DEA's pronouncements in response to individual *ex parte* correspondence (creating an "underground regulation"). At a minimum, the DEA would need to first issue a formal order and publish it to the Federal Register (per 21 USC §811(e) and 21 CFR §1308.47).

(C) Given the foregoing issues with the Proposed Definition, BayMedica is deeply concerned that the DEA will attempt to surreptitiously schedule other Non-Intoxicating Cannabinoids as Schedule I Tetrahydrocannabinols, Depriving BayMedica of Due Process Rights, and Potentially Rendering Some or All of its Business Federally Unlawful

BayMedica is deeply concerned that the DEA will attempt similar end runs around the CSA to surreptitiously schedule other Non-Intoxicating Cannabinoids as Schedule I Tetrahydrocannabinol. As with its attempts to schedule THCA on the fly, this would be contrary to Congress' intent in establishing procedures under the CSA for the scheduling the immediate precursors of scheduled controlled substance, its intent in defining controlled substance analogues under the Federal Analogue Act, its intent in specifically scheduling THC for its



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intoxicating pharmacological properties, and settled law per valid federal Circuit Court precedents.

Federal appellate precedents established prior to the 2018 Farm Bill are instructive on this point as they have addressed previous attempts by the DEA to expand the definition of "tetrahydrocannabinol," and are still valid law¹⁵ notwithstanding the passage of the 2018 Farm Bill. In *Hemp Indus. Ass'n v. DEA*,¹⁶ a trade association representing numerous manufacturers and importers of non-psychoactive hemp foodstuffs challenged DEA Final Rules which sought to expand the definition of "Tetrahydrocannabinols" to include any naturally occurring THC regardless of whether such THC is derived from marihuana or hemp (which was more narrowly defined at the time to exclude the flowering tops and resin derived therefrom, but still federally lawful if cultivated outside the United States) and would have effectively prohibited the theretofore lawful importation and sale of such non-psychoactive hemp foodstuffs with even trace amounts of THC.¹⁷ In its ruling in *Hemp Indus. Ass'n v. DEA*, the Ninth Circuit permanently enjoined the DEA from enforcing the CSA against manufacturers and importers of such products through the DEA's expanded definition for Tetrahydrocannabinols.

The *HIA* court held that the DEA could not prohibit trace amounts of hemp-derived THC on the basis that THC (which at the time was specifically defined by DEA regulations as being synthetically-derived) and marijuana (containing naturally-occurring THC) were both deemed Schedule I controlled substances, and would first need to formally schedule hemp-derived THC before it could prohibit the importation of hemp foods due to trace amounts of THC. In its holding, the Ninth Circuit stated that while the DEA could "regulate foodstuffs containing natural THC if it is contained within marijuana, *and* can regulate synthetic THC of any kind ... they *cannot regulate naturally-occurring THC not contained within or derived from marijuana—i.e., non-psychoactive hemp products—because non-psychoactive hemp is not included in Schedule I,*" concluding in no uncertain terms that "*[t]he DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance.*"¹⁸

Should BayMedica be permitted to appear at the hearing, we intend to submit Exhibit A to this Notice into the record as evidence of a material issue of fact, as well as the various sources cited in the endnotes to this Notice. Additionally, Shane Johnson, MD, BayMedica's Senior Vice President & General Manager, is willing to present his expert opinion at the hearing in support of BayMedica's position. Shane holds a Bachelor of Science in Neuroscience from Brown University, and a Medical Degree from Stanford University. He is a founder of BayMedica and is well versed in the utility of cannabinoids in the health and wellness sector, as well as the various approaches to producing nature-identical cannabinoids including extraction,



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semi-synthesis from hemp derived starting materials, and full synthesis using both chemistry and/or biosynthesis.

Please send all notices regarding this Notice of Appearance to the following addressees:

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500 Capitol Mall, Suite 2350
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Shane Johnson, MD
Senior Vice President & General Manager
BayMedica, LLC
930 Tahoe Blvd., Ste. 802-433
Incline Village, NV 89451
sjohnson@baymedica.com

Respectfully yours,

A handwritten signature in blue ink, appearing to read "Khurshid Khoja", written in a cursive style.

Khurshid Khoja, Esq.

cc: Shane Johnson, MD

¹ Though BayMedica is also a member of the National Cannabis Industry Association ("NCIA"), the views presented herein are BayMedica's, and should not be attributed to NCIA. That said, there are no doubt other persons in the cannabis industry that are similarly situated to BayMedica and would also be adversely affected by the Proposed Rule.

² See "InMed Pharmaceuticals Reports Full Year Fiscal 2024 Financial Results and Provides Business Update," *Yahoo Finance*, Sept. 30, 2024: (<https://finance.yahoo.com/news/inmed-pharmaceuticals-reports-full-fiscal-120000533.html>).

³ Note that BayMedica can show that they are "person adversely affected or aggrieved by" the Proposed Rule (as this phrase is employed in the definition of "interested person" under 21 CFR 1300.01(b)) by showing that they meet the standard set in section 10(a) of the Administrative Procedure Act for being "adversely affected or aggrieved by" an agency action, *notwithstanding* the fact that they are not invoking standing to seek judicial review of a final agency rule. In other words, if BayMedica can demonstrate that they would be "adversely affected or aggrieved by" if the Proposed Definition were codified in a final DEA rule, they can demonstrate the same with respect to the Proposed Rule as well. See *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1200 (9th Cir. 2004). In *Sausalito* the court instructs that "if statutory standing is not explicitly provided in the text of a statute," or in our case 21 CFR 1300.01(b), "a [party] challenging federal administrative action looks to Section 10(a) of the Administrative Procedure Act (APA), which provides that any 'person ... adversely affected or aggrieved by agency



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action within the meaning of a relevant statute, is entitled to judicial review thereof.' 5 U.S.C. § 702." *Id.* Additionally, under 21 CFR 1300.01(b)), a "person" is not limited to individuals and includes "any ... corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."

⁴ See *Idaho ex rel. Kempthorne v. U.S. Forest Serv.*, 142 F. Supp. 2d 1248, 1255 (D. Idaho 2001): "Section 10(a) of the APA provides that 'a person ... adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.' 5 U.S.C. § 702. In cases arising under the APA, the standing requirement has been read to mean that plaintiffs must show 'the challenged action ha[s] caused them injury in fact' and that the injury is 'to an interest arguably within the zone of interests to be protected or regulated by the statutes that the agencies were claimed to have violated.' *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1514 n. 12 (9th Cir.1992)."

⁵ See *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1200 (9th Cir. 2004):

Interpreting the APA, the Supreme Court in *Association of Data Processing Service Organizations v. Camp*, 397 U.S. 150, 153, 90 S.Ct. 827, 25 L.Ed.2d 184 (1970), held that anyone "arguably within the zone of interests" protected by the statute under which he or she has asserted injury has standing to bring suit under that statute. The Court has instructed that the "zone of interests" test is to be construed generously, stating that the "test is not meant to be especially demanding," and that a court should deny standing under the "zone of interest" test only "if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke v. Secs. Indus. Ass'n*, 479 U.S. 388, 399, 107 S.Ct. 750, 93 L.Ed.2d 757 (1987); see also *Thinket Ink Info. Res., Inc. v. Sun Microsystems, Inc.*, 368 F.3d 1053, 1059 (9th Cir.2004); *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1120–21 (9th Cir.2004). Specifically, "there need be no indication of congressional purpose to benefit the would-be plaintiff." *Graham v. Fed. Emergency Mgmt. Agency*, 149 F.3d 997, 1004 (9th Cir.1998) (citing *Clarke*, 479 U.S. at 399–400, 107 S.Ct. 750).... To determine whether [a party] is within the zone of interests of the statutes under which it brings suit, we look "to the substantive provisions of the [statutes], the alleged violations of which serve as the gravamen of the complaint." *Bennett v. Spear*, 520 U.S. 154, 175, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997). We are instructed by *Clarke* to understand these substantive provisions liberally. Thus, "APA plaintiffs need only show that their interests fall within the 'general policy' of the underlying statute, such that interpretations of the statute's provisions or scope could directly affect them." *Graham*, 149 F.3d at 1004 (quoting *Nat'l Credit Union Admin. v. First Nat'l Bank and Trust Co.*, 522 U.S. 479, 487–88, 118 S.Ct. 927, 140 L.Ed.2d 1 (1998) (further citations omitted)).

⁶ See 5 U.S.C. § 702.

⁷ See DEA's Rule *Interpretation of Listing of "Tetrahydrocannabinols" in Schedule I* (10/09/2001), Docket No. DEA-204, 66 FR 51530 <https://www.federalregister.gov/d/01-25022/p-40> .

⁸ See 21 U.S.C. §802(32)(A):



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(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance-

(i) the chemical structure of which is *substantially similar* to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is *substantially similar* to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include-

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

⁹ See DEA Proposed Rule Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in Schedule I, (03/30/2021), Docket No. DEA-491, 86 FR 16553, <https://www.federalregister.gov/documents/2021/03/30/2021-06553/schedules-of-controlled-substances-placement-of-5f-edmb-pinaca-5f-mdmb-pica-fub-akb48#p-31> .

¹⁰ See DEA's Proposed Rule Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, Docket No. DEA-496, 84 FR 48815.

¹¹ See Exhibit A to BayMedica Notice of Appearance (May 13, 2024 Letter from Dr. Terry Boos).



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¹² See the USDA's *Laboratory Testing Guidelines U.S. Domestic Hemp Production Program* available at <https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories/lab-testing-guidelines>

¹³ See *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682 (9th Cir. 2022); see also Letter from Terrence L. Boos, Chief, Drug & Chem. Evaluation Section, Diversion Control Div., U.S. Dep't of Just. Drug Enf't Admin., to Donna C. Yeatman, Exec. Sec'y, Ala. Bd. of Pharmacy (Sept. 15, 2021), <https://hempindustrydaily.com/wp-content/uploads/2021/11/DEA-letter-to-AL-BOP.pdf>.

¹⁴ See <https://www.federalregister.gov/documents/search?conditions%5Bagencies%5D%5B%5D=drug-enforcement-administration&conditions%5Bterm%5D=Tetrahydrocannabinolic+Acid>

¹⁵ The holding *Hemp Indus. Ass'n v. DEA* is still the current law, as the DEA did not appeal the Ninth Circuit's decision to the U.S. Supreme Court.

¹⁶ *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012 (9th Cir. 2004).

¹⁷ See the DEA's Rule re *Clarification of Listing of "Tetrahydrocannabinols" in Schedule I*, DEA 205-F (published March 21, 2003), 68 Fed. Reg. 14114, and its Rule re *Exemption From Control of Certain Industrial Products and Materials Derived From the Cannabis Plant*, DEA 206-F (published March 21, 2003), 68 Fed. Reg. 14119.

¹⁸ *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1018 (9th Cir. 2004) (emphasis added).

EXHIBIT A to Notice of Appearance by BayMedica, LLC (Docket No. DEA-1362)



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

www.dea.gov

May 13, 2024

Mr. Shane Pennington
Porter Wright Morris & Arthur LLP
2020 L Street, NW Suite 600
Washington, D.C. 20006

Dear Mr. Pennington:

This is in response to your letter dated April 25, 2024, in which you requested the control status of tetrahydrocannabinolic acid (THCA) under the Controlled Substances Act (CSA). For THCA, we are assuming THCA is referencing delta-9-THCA. The Drug Enforcement Administration (DEA) conducted a review of the CSA and its implementing regulations with regard to these questions.

The CSA classifies tetrahydrocannabinols (such as THCA) as controlled in schedule I. 21 U.S.C. § 812, Schedule I(c)(17); 21 CFR 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term “tetrahydrocannabinols” means those “naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.” 21 CFR § 1308.11(d)(31). Thus, tetrahydrocannabinols synthetically produced from non-cannabis materials is controlled under the CSA as a “tetrahydrocannabinol.”

The CSA, however, excludes “hemp” from the definition of marihuana and the classification of tetrahydrocannabinols in Schedule I. 21 U.S.C. 802(16)(B)(i); 21 U.S.C. 812, Schedule I(c)(17). The term “hemp” is “the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. § 1639o.

Accordingly, naturally occurring tetrahydrocannabinols extracted from the cannabis plant that have a delta-9-tetrahydrocannabinol (delta-9-THC) concentration of not more than 0.3 percent on a dry weight basis meet the definition of “hemp” and thus are not controlled under the CSA. Conversely, a naturally derived cannabinoid having a delta-9-THC concentration more than 0.3 percent on a dry weight basis is controlled in schedule I under the CSA as marihuana.

In regards to THCA, Congress has directed that, when determining whether a substance constitutes hemp, the delta-9-THC concentration is to be tested “using post-decarboxylation or other similarly reliable methods.” 7 U.S.C. § 1639p(a)(2)(A)(ii); 7 U.S.C. § 1639q(a)(2)(B). The “decarboxylation” process converts delta-9-THCA to delta-9-THC. Thus, for the purposes of

Mr. Shane Pennington

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enforcing the hemp definition, the delta-9-THC level must account for any delta-9-THCA in a substance. Accordingly, cannabis-derived THCA does not meet the definition of hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9-THC.

If you have any further questions, please contact the Drug and Chemical Evaluation Section at DPE@dea.gov.

Sincerely,



Terrence L. Boos, Ph.D., Chief
Drug & Chemical Evaluation Section
Diversion Control Division

Cc: Washington Division Office

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ, or Administrator
8701 Morrisette Dr., Springfield, VA 22152.
nprm@dea.gov

Subject: Notice of Appearance

Dear Sir/Ma'am:

Please take notice that Mr. Jason Greninger will appear in the matter of: Docket No. DEA-1362.

(A) An administrator, researcher, data analyst, and career patient advocate and Legislative & Congressional Outreach Coordinator for CPR/CC Coalition for Patients Rights / Compassion Center, a pioneering medical management services organization (MSO), and (CBCCERN) Community-Based Clinical Cannabis Evaluation & Research Network and the Center for Incubation & Findings Research (CIFR)

CBCCERN serves as the first-of-its kind platform to provide organization, administration and oversight on organized peer-reviewed research of the cannabis plant, its various individual compounds and various preparations, through National networks of (Endo)Cannabinologists, Researchers and Licensed Clinicians who are also currently in the practice of recommending medical cannabis for the treatment and alleviation of disorders that are not well addressed by existing FDA-approved therapies. Today, CBCCERN is under the Compassion Center and the Center for Incubation & Findings Research where it leads a variety of outreach and clinical efforts related to widespread adoption of its network. A major part of the Teach1Serve10.org Free Clinic System, CBCCERN trains, manages and oversees the medical cannabis clinical practicums, medical cannabis recommendations and registration with the state, credentialing, patient advocacy and interprofessional continuing medical education development organization focusing on expanding patient access to medical cannabis, and based in Oregon. As the oldest medical cannabis clinic still in existence, Compassion Center has been at the forefront of improving the quality of life for medical cannabis patients by facilitating access to state-managed programs since June of 2001. Today, Compassion Center's providers evaluate patients, and subsequently provide qualifying patients with recommendations, referrals and/or registrations for states that medical cannabis is authorized under law and currently supports expanding medical cannabis programs in 18 states.

Our efforts have directly guided over 15,000 Oregonians in reducing their dependence on opioid pain management and alleviating intractable neurological conditions, and have since assisted a countless number of others across the U.S. through continuing medical education and referrals, and as previously stated, we even provide clinical access to patients in eighteen states. Drawing from this extensive experience, we will provide critical insights, data, and professional opinions on the current state of the cannabis industry, product purity standards, patient safety issues and diversion into the illicit "black" market. Additionally, we will address potential impacts of cannabis rescheduling, offering unique perspectives that can help the DEA, and any other government agencies, protect our patients, providers, facilities and institutions effectively, while maintaining a wide range of liberties and justice for all Americans.

(B) Cannabis has literally been used for thousands of years as G.R.A.S. (Generally Regarded As Safe), for animal feed and as medicine, but never before have farmers had access to, nor the desire to use chemical additives in the production of their crops.. However, due a variety of factors ranging from a diminishing agricultural workforce and depleted soils to otherwise predatorial and often deceptive marketing practices in the agricultural industry regarding genetically modified crops, chemicals, pesticides, additives and/or hormones, leading farmers to achieve "easy ways to amplify yields", we face a myriad of concerning factors with regards to purity, safety, potency and efficacy. In the recreational cannabis space, specifically, plant growth regulators (PGRs) are regularly used to regulate and manipulate cellular processes in the plant cells that are targeted, in order to boost their yields. PGRs have evidently become an issue for medical cannabis patients as their cannabis farmers are becoming more and more dependent upon the technology and less dependent upon the land, permaculture and people. It is therefore a constitutional issue on the personal access to a simple plant that was previously; and by all current definitions, designated as G.R.A.S. (Generally Regarded As Safe)

(C) 1) Discussion of supportive testimony to add to this hearings evidence include, congressional records of the committee discussions with the AMA regarding the marijuana Act prior to the vote, the congressional records of the floor discussions regarding the AMA prior to the vote, congressional records specific to the DEA, DOJ, and cannabis/marijuana, and U.S. patents records regarding cannabinoids.

2) Supportive of responsible descheduling as cannabis fits within all FDA requirements and definitions of G.R.A.S. and designated as evidence; and as such historically and by the current FDA rules for G.R.A.S use before 1958; thus taking a variety of considerations into account in order for allopathic, integrative and traditional health practitioners, and other pharmaceutical industry stakeholders to safely integrate the cannabis plant into the continuum of care, further protecting cannabis patients by preventing the plants from being adulterated or isolated in ways that either reduce efficacy or create safety issues that must be addressed in emergency rooms.

All notices to be sent pursuant to this appearance should be addressed to:

Compassion Center
% James Creel, PgM
P.O. Box 868
Clackamas, OR 97015

Respectfully yours


Jason Greninger

CPR/CC Legislative & Congressional Outreach Coordinator
Compassion-Center.org
Jason.Greninger@MyCPR.US
702-401-8620

Dean, Delonda

From: Coss Marte <coss@conbud.com>
Sent: Monday, September 30, 2024 5:44 AM
To: NPRM
Subject: [EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Coss Marte
CEO/ Founder
121 Ludlow Street 2nd Fl.
New York, NY 10002
<http://www.conbody.com/>

TEDx Talk

**Compassion Center**

PO Box 868, Clackamas, OR 97015

www.Compassion-Center.org**1-844-842-COMPASSION**

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ, or Administrator
8701 Morrisette Dr., Springfield, VA 22152.

Subject: Notice of Appearance

Dear Sir/Ma'am:

Please take notice that Ms. Stormy Ray will appear in the matter of: Docket No. DEA-1362.

(A) Co-petitioner of the Oregon Medical Marijuana Act (OMMA) and career patient advocate for the Stormy Ray Cardholders' Foundation (SRCF), and Compassion Center, is a pioneering leader in medical cannabis. In her thirty plus years of advocacy, Stormy has aided in the creation of a consortium of educators, advocates and clinicians dedicated to patient advocacy, clinical services, and the development of interprofessional continuing medical education aimed at bridging gaps in medical cannabis, integrative healthcare and mental health. The organizations are committed to expanding patient access to medical cannabis and other plant-based medicines within the continuum of care and are based in Oregon. As one of the oldest, if not the oldest, medical cannabis clinics still in existence, Compassion Center has been at the forefront of improving the quality of life and the standard of care for all qualifying medical cannabis patients, and the SRCF continues to advocate on their behalf. Since June 1995, Stormy Ray, the chief executive of SRCF, has educated and advocated on behalf of patients and remains free from conflicts of interest associated with commercial entities, in line with the industry standard for education.

Today, the Compassion Center's providers evaluate patients, and subsequently provide qualifying patients with recommendations, referrals and/or registrations for 18 states where the cannabis plant has been authorized under state law. The Compassion Center currently supports the expansion of medical cannabis programs with individualized patient-specific treatment plans that typically include recommending dosages, frequency, cultivar and/or delivery mechanisms, supporting integrations with the patient's primary clinicians and/or interprofessional healthcare providers, taking in account each of their existing pharmaceutical contraindications, activities of daily living, nutrition/diet, genetic predispositions and more ensuring positive, safe and effective outcomes.

Our efforts have directly helped over 15,000 Oregonians reduce their dependence on opioid pain management and alleviate intractable neurological conditions. This success has empowered Compassion Center to publish our findings and implement logical solutions in Oregon, California, and beyond. We have since assisted with countless others across the U.S. by developing and presenting interprofessional continuing medical education, producing clinical practicums, and offering free clinics with referrals. Most recently, Compassion Center and CIFR presented two of the 250 lectures at the VA Suicide Prevention Conference 2024 in Portland, OR. Our presentations highlighted the benefits of integrating multiple disciplines to optimize biophysical wellness, increase activities of daily living, and introduce new methodologies for reducing suicides and homicides.

Drawing from this extensive experience, SRCF, CIFR and Compassion Center will provide the DEA with testimony, focusing on critical insights, datasets, and professional opinions on the current state of the cannabis industry, product purity standards, patient safety issues and more. Recognizing the DEA's mission to eliminate diversion into the illicit "black" market, Compassion Center will provide suggestions that can completely eliminate the black market/illicit market in its entirety. Additionally, Compassion Center will address potential benefits, impacts and risks that are associated with cannabis rescheduling, offering unique perspectives that



can help the DEA, and any other government agencies, protect our patients, providers, facilities and/or institutions from harm, effectively, while maintaining a wide range of liberties and justice for all Americans.

(B) Cannabis has literally been used for thousands of years, as medicine, but never before have farmers had access to, nor the desire to use chemical additives in the production of their crops. At least, not as much as they do today, and have adapted to over the last hundred or so years. However, due a variety of factors ranging from a diminishing agricultural workforce and depleted soils to otherwise predatory and often deceptive marketing practices in the agricultural industry regarding genetically modified crops, chemicals, pesticides, additives and/or hormones, leading farmers to achieve “easy ways to amplify yields”, we face a myriad of concerning factors with regards to purity, safety, potency and efficacy. In the recreational and, unfortunately, the medical cannabis spaces, specifically, plant growth regulators (PGRs) are regularly used to regulate and manipulate cellular processes in the plant cells that are targeted, in order to boost their yields. PGRs have evidently become an issue for medical cannabis patients as their cannabis farmers are becoming more and more dependent upon the technology and less dependent upon the land, permaculture and people, leading to unintended side effects and consequences. This is not isolated to farmers using synthetics in growth, and carries over to those using synthetic cannabinoids in place of whole plant profiles leading to what is commonly referred to as the bell curve, and an increasing tolerance and immunity to the synthetic forms of the cannabis plant.

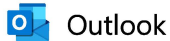
(C) Supportive of descheduling altogether, taking a variety of considerations into account in order for allopathic, integrative and traditional health practitioners, and other pharmaceutical industry stakeholders to safely integrate the cannabis plant into the continuum of care without having to lose ground on what has been created over the last thirty or so years.

All notices to be sent pursuant to this appearance should be addressed to:

Compassion Center
% Stormy Ray
P.O. Box 868
Clackamas, OR 97015

Respectfully yours,

/s/ Stormy Ray
Patient Advocate
Compassion Center
admin@compassion-center.org
Office: 541-484-6558 Ext 707



Outlook

[EXTERNAL] Notice of intention to participate in hearing

From Legal Marijuana Now Party <admin@legalmarijuanawmn.org>

Date Mon 9/30/2024 10:34 AM

To NPRM <NPRM@dea.gov>

Notice of intention to participate in hearing

To: Drug Enforcement Administration Representative,

(1) State with particularity the interest of the person in the proceeding;

My name is Dennis Schuller I a cannabis activist and the the chairman of the Legal Marijuana Now party in Minnesota. We strongly endorse any effort to eliminate the discrimination associated with marijuana. Any movement towards deregulating marijuana including the push to move it to a schedule 3 "drug" on the DEA classification table is good. I speak for many who have been affected by these laws. I have been affected through these laws by government fees/tickets, law enforcement intimidation, employment drug testing, social stigma and denial of constitutional rights to life, liberty and the pursuit of happiness.

(2) State with particularity the objections or issues concerning which the person desires to be heard; and

The drug enforcement agency (DEA) and their non governmental drug schedule as it is currently known and laws against marijuana and marijuana use are discriminatory. The DEA is without basis as marijuana should never have been a focus and the DEA itself was created knowing that marijuana was not "particularly harmful" (Richard Nixon). The testimony of Harry Anslinger in front of congress against marijuana was full of disparaging remarks about race, sexual promiscuity, graven drug induced psychosis and has all been proven false and contrary to known health benefits of marijuana. Harry Anslinger disgraced himself with his testimony in front of congress and later turned to morphine for comfort while his health condition worsened

(3) State briefly the position of the person regarding the objections or issues.

My position is that I believe in a government that helps the people. However I believe there are ways to help people without trampling on the rights of others especially when it comes to an individuals right to grow a garden and use traditional herbal remedies.

Sincerely

Dennis Schuller
6128668424



September 30, 2024

Drug Enforcement Administration, Attn: Administrator/Hearing Clerk/OALJ
8701 Morrisette Drive, Springfield, VA 22152

Subject: Notice of Appearance - Drug Policy Alliance - Docket No. DEA-1362

Dear Sir or Madam,

Please take notice that the Drug Policy Alliance (DPA) will appear in the matter of Docket No. DEA-1362.

DPA is the leading organization in the U.S. working to end the drug war, repair its harms, and build a non-punitive, equitable, and regulated drug market, grounded in evidence, health, equity, and human rights.

As an organization that collaborates closely with individuals and communities impacted by criminalization, as well as veterans, medical patients, adult consumers, noncitizens, small businesses, organized labor, and state governments, we are deeply invested in the policy gap between federal and state cannabis laws.

Through our leadership in the United for Marijuana Decriminalization coalition, DPA spearheaded the submission of over 10,000 public comments on the Department of Justice's proposed rule to reschedule marijuana. The stakeholders we engaged represent those disproportionately impacted by federal cannabis criminalization and those advocating on their behalf -- all of whom support federal marijuana decriminalization which requires descheduling (removing) cannabis from the schedules of the Controlled Substances Act entirely.

DPA qualifies as an interested party under 21 C.F.R. §§ 1300.01(b), 1308.44, and would be adversely affected or aggrieved by rescheduling marijuana. Moving marijuana to Schedule III would perpetuate federal criminalization while imposing new restrictions on access, diverting DPA's resources and requiring additional funds to protect vulnerable populations from the continued harms of criminalization. This includes individuals who use marijuana and the communities that have suffered most under its enforcement.

Rescheduling marijuana would also force DPA to redirect its advocacy and informational efforts, requiring new initiatives to educate stakeholders, including the public, policymakers, and regulators, on the additional restrictions and anticipated harms under Schedule III. These efforts would demand significant resources, further detracting from our current work.

The purpose of the hearing is to "receiv[e] factual evidence and expert opinion regarding" whether marijuana should be transferred to Schedule III of the list of controlled substances. DPA is uniquely positioned to provide this expert opinion based on our extensive role in advancing marijuana reforms and educating stakeholders over the past two decades.

DRUG POLICY ALLIANCE

131 West 33rd Street • 15th Floor • New York, NY 10001
212.613.8020 • contact@drugpolicy.org

drugpolicy.org



Therefore, we respectfully request the opportunity to present evidence on the following critical subjects identified by the DEA:

1. **Currently Accepted Medical Use (CAMU)**

DPA supports HHS and DOJ's recognition of marijuana's currently accepted medical use. The reliance on state regulation in determining CAMU is critically significant, as the DEA's previous narrow interpretation, as noted in the OLC memo, ignored widespread clinical experience sanctioned by state medical licensing regulators. At a public hearing, DPA would present additional evidence underscoring the importance of state laws and regulations in recognizing marijuana's medical use.

2. **State Regulation**

State laws and regulations were essential to HHS's recommendation and DOJ's decision to reschedule marijuana. However, their analysis failed to fully consider the broader impact of state regulation on marijuana use, public health, and illegal activity—factors foundational to determining marijuana's scheduling. At a public hearing, DPA would present detailed evidence on how state regulation has influenced these critical aspects of the agencies' eight-factor analysis.

3. **Marijuana's Actual or Relative Potential for Abuse**

While DPA agrees with the recognition that marijuana does not have a high potential for abuse, the failure to account for state-level regulation's impact on abuse potential is a significant oversight. At a public hearing, DPA would present evidence demonstrating that state regulation has reduced marijuana's potential for abuse and how it should be factored into the agencies' evaluations of abuse patterns, scope, and significance.

4. **Marijuana's Risk to Public Health**

The agencies' evaluation of marijuana's public health risks is incomplete, particularly in its failure to consider how state regulation has mitigated these risks. At a public hearing, DPA would present evidence showing the positive effects of state regulations on public health and the detrimental impacts of federal criminalization, including how maintaining marijuana criminalization will prevent research that could produce valuable public health knowledge.

5. **Marijuana's History or Pattern of Abuse**

The agencies' historical analysis of marijuana control omitted critical considerations about the racist origins of federal marijuana criminalization and its enforcement. At a public hearing, DPA would present evidence of this history, including the roles of figures like Harry Anslinger and President Nixon, to provide a more comprehensive understanding of marijuana's history and pattern of abuse. DPA would also provide evidence that illustrates how racism drove marijuana's placement on the Controlled Substances Act and resulted in enumerable harms and racial disparities, which continue today and would continue if marijuana were rescheduled as a Schedule III drug.

6. **Regulatory Analysis**

The DOJ's decision to forego consideration under several Executive Orders, including those related to civil justice, federalism, and Tribal governance, is concerning. Rescheduling marijuana to Schedule III would perpetuate racial disparities, conflict with state laws, and undermine Tribal autonomy. At a public hearing, DPA would provide evidence highlighting the significant civil

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justice, federalism, and Tribal sovereignty implications that warrant serious consideration as a part of this proposed rule.

In conclusion, DPA strongly believes that marijuana must be descheduled from the Controlled Substances Act (CSA) and regulated to protect public health, end federal criminalization, and resolve the ongoing conflict between federal and state marijuana laws. We request the opportunity to present evidence at a public hearing to further support these points.

Thank you for your consideration.

All notices to be sent pursuant to this appearance should be addressed to:

Cat Packer
1796 Bar Harbor Rd
Columbus, OH 43219
Respectfully yours,

A handwritten signature in black ink that reads "Cat Packer" with a horizontal line extending from the end of the name.

Cat Packer

Director of Drug Markets and Legal Regulation
Drug Policy Alliance

DRUG POLICY ALLIANCE

131 West 33rd Street • 15th Floor • New York, NY 10001
212.613.8020 • contact@drugpolicy.org

drugpolicy.org

September 30, 2024

Drug Enforcement Administration: Attn: Hearing Clerk/OALJ

Ellen@GreenPathTraining.com

Subject: Notice of Appearance

Dear Sir,

Please take notice that Ellen Brown will appear in the matter of Docket No. DEA-1362.

- A. I'm interested in the proceedings as a cannabis expert. I'm serving as the expert of cannabis cultivation for the state of Massachusetts. I'm on the Massachusetts Cannabis Advisory Board. I'm the chair of the Research Subcommittee for the Cannabis Advisory Board. I'm also an honorably discharged United States Air Force Veteran. As a Veteran and cannabis expert I'm very interested in this hearing and its outcome.
- B. I'd greatly appreciate the opportunity to be heard in support of rescheduling cannabis from schedule one to schedule three.
- C. My position is that cannabis should be rescheduled to schedule three to allow for cannabis research and because cannabis does have medical use and value. Rescheduling cannabis from schedule one to schedule three would greatly benefit the United States Veteran Population. As a subject matter expert, I believe my testimony would be insightful and helpful in making the decision.

All notices to be sent pursuant to this appearance should be addressed to:

Ellen Brown

48 Sconset Circle

Sandwich MA

02563

Respectfully Yours,

Ellen Brown

September 30, 2024

Drug Enforcement Administration

Attn: Hearing Clerk/OALJ

VIA EMAIL

Subject: Notice of Appearance

Dear Sir:

Please take notice that Erin Gorman Kirk, Esquire) will appear in the matter of: Docket No. DEA-1362.

(A) I am the Cannabis Ombudsman for the State of Connecticut, charged with assisting and advocating for medical patients. Connecticut legalized medical cannabis in 2012.

(B) We agree with Department of Health and Human Services (HHS) recommendation on the rescheduling of marijuana, wish to help decision-makers understand the importance this decision will have for our hero Veterans, cancer patients, those with debilitating medical ailments, and patients who want to be able to utilize plant-based medication rather than highly addictive opioids. We want to press the issue of insurance companies reimbursing patients for their medication and promote ending of the artificial stigma created by the War on Drugs.

(C) Our position based on the 58,000 plus medical card holders who have at one time been in our program is to reschedule marijuana as recommended by HHS, that marijuana has a currently accepted medical use, has a potential for abuse less than the drugs or other substances in schedules I and II, and that its abuse may lead to moderate or low physical dependence or high psychological dependence.

All notices to be sent pursuant to this appearance should be addressed to:

Erin Gorman Kirk
747 Old Stamford RD
New Canaan, CT 06840

Respectfully yours,

Erin Gorman Kirk

September 30, 2024

Esaia González

Council Member

Veterans Action Council

Apt 622 Greenbriar Circle

Petaluma, CA 94954

(619)241-6632

To Whom It Will Concern,

619-241-6632 - FROM THE DESK OF Esaia González -

EMAIL: soijana@proton.me, esaiagonzalez@gmail.com

30 Sept 2024, I hereby give notice that I wish to present and argue my position during the upcoming Hearing by an Administrative Law Judge on cannabis rescheduling:

RE: Schedules of Controlled Substances: Rescheduling of Marijuana — Hearing on the Proposed Rule by the Drug Enforcement Administration

<https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana>

I am a disabled United States Marine Corps Veteran, and the proposed rule will harm me.

Esaia González — Written Notice as interested party:

I have suffered injury from schedule #1 placement of cannabis, and while schedule #3 rescheduling will resolve some of these issues; I will still continue to suffer unnecessary harm and continued injury under the proposed schedule #3.

Schedule #3 is unacceptable, given the totality of the evidence and experience we have from the many states medicinal cannabis and adult recreational cannabis access programs, as well as academic and scientific record.

State medicinal access programs and adult recreational access programs operate in a consensus fashion under state laws that more closely align with schedule #5 than schedule #3.

The Department of Veterans Affairs - Hospital System, given the fact that schedule #3 will require time consuming FDA approval before such medicines will be able to be dispensed from VA pharmacies will not be able to integrate cannabis into Veterans' pain management or Post Traumatic Stress treatment as they certainly would be able to under a schedule #5 placement or by de-scheduling.

Veterans Affairs hospitals, under schedule #3, will not be able to facilitate cannabis prescriptions until FDA approves new cannabis medicines. Such FDA approvals will be granted for products based upon the many preparations available in dispensaries operated under state laws. This process is onerous, and it takes many years for FDA approval for a similar product that is already widely available from said dispensaries.

Schedule #5 placement will allow my VA doctor to prescribe/recommend my cannabis medication and for the Veterans Affairs Administration to pay for the product that I would then purchase myself in much the same way that Veterans currently receive a clothing allowance and then buy their own clothes.

Current VA policy spells out how a doctor's VA, because of schedule #1 placement of cannabis, cannot write a 'recommendation' for cannabis. This VA policy has made it necessary for me, a 100% total and permanently rated disabled Veteran, to have to leave the VA and create a new doctor relationship outside the VA hospital system at my own expense. Suppose cannabis is placed in schedule #3. In that case, my situation will be only partially repaired as I will then be able to, for the first time, have a VA doctor write my 'recommendation' for cannabis but will still have to pay for my medication out of pocket even though all of my other medications stemming from my service-connected injuries are covered by the VA.

Schedule #5 is more appropriate - follow the experience, not just the evidence and law, Given the experience in the 30+ states and territories enacting such laws since 1996 and the fact that medical boards, state legislatures, hospital systems, nurses associations, patients, their families, and their Communities have carefully thought through the many access issues and have converged on a consensus policy supporting over-the-counter access, which the DEA should instead reschedule to schedule #5 to reflect this reality.

It should be noted that connected to the 30,000 medical care providers and the 6,000,000 patients acknowledged by the FDA, accessing cannabis through a state-authorized medical cannabis recommendation is a mountain of real-world experience. The FDA makes a conservative opinion based on evidence, but the experience is what the FDA lacks; the DEA should recommend based on experience, law, and evidence.

I ask the court to rule that the DEA reschedule cannabis to Schedule #5 or deschedule outright, reflecting its medicinal potential, the overwhelming evidence of its benefits as well as the experience of the millions of patients and their communities. This experience includes state panels dedicated to hearings on various cannabis subject matters.

The conclusion of these many million human hours in the many states has resulted in what we experience today: a consensus around handling cannabis as an over-the-counter medication. I have participated in some of these state processes and can attest to the professionalism of the membership and the seriousness under which they carried out their tasks. These are well-thought-through, experience-based recommendations that stand toe-to-toe with any evidence-based evaluation of the FDA.

Background documents & Links:

‘Cannab's’ ontol'gies: Conceptual issues with Cannabis and cannabinoids terminology
:

<https://journals.sagepub.com/doi/10.1177/2050324520945797>

Cannabis amnesia – Indian hemp parley at the Office International d’Hygiène Publique in 1935: https://www.researchgate.net/publication/360540702_Cannabis_amnesia_-_Indian_hemp_parley_at_the_Office_International_d'Hygiene_Publique_in_1935

Veterans Action Council Green Paper:

<https://www.veteransactioncouncil.com/the-green-paper-1>



September 30, 2024

VIA ELECTRONIC SUBMISSION – NPRM@DEA.GOV

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Re: Notice of Appearance (Docket No. DEA-1362)

Administrator Milgram:

Please take notice that Green Thumb Industries Inc. (“GTI”) requests to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the “Proposed Rule”), if DEA grants GTI’s request to participate in the hearing scheduled for December 2, 2024.

(A) GTI has standing to participate in a hearing. GTI is an “interested person” and falls within the CSA’s zone of interests. Further, GTI will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized. GTI’s status as an “interested person” is further detailed in the enclosed submission.

(B) Among other things, GTI has unique expertise and would provide invaluable insights into: (i) the practical consequences of rescheduling, including the economic impact of 280E and its direct effect on public health and safety; (ii) the impact of new marijuana-specific DEA controls on GTI and its vendors and customers; and (iii) marijuana’s currently accepted medical use in treatment in the states in which GTI operates. Further detail about the objections or issues on which GTI desires to be heard is provided in the enclosed submission.

(C) As a national cannabis consumer packaged goods company and retailer, GTI has knowledge and experience regarding the impact of DEA controls on regulated businesses. Moreover, GTI has expertise in the medical markets in which it operates and thus can speak directly to marijuana’s medical use in treatment in the United States. GTI’s positions with regard to the particular issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to the attorneys at the addresses provided below.

Administrator Milgram
September 30, 2024

Page 2

Respectfully yours,



Andrew J. Kline
PERKINS COIE LLP
1900 Sixteenth Street, Suite 1400
Denver, CO 80202-5255
AKline@perkinscoie.com

Barak Cohen
PERKINS COIE LLP
700 Thirteenth Street NW, Suite 800
Washington, DC 20005
BCohen@perkinscoie.com

Thomas J. Tobin
PERKINS COIE LLP
1301 Third Avenue, Suite 4900
Seattle, WA 98101
TTobin@perkinscoie.com

Enclosure



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1900 Sixteenth Street
Suite 1400
Denver, CO 80202-5255

T. +1.303.291.2300
F. +1.303.291.2400
perkinscoie.com

September 30, 2024

Andrew J. Kline
AKline@perkinscoie.com
D. +1.303.291.2307
F. +1.303.291.2407

VIA ELECTRONIC SUBMISSION – *NPRM@DEA.GOV*

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

**Re: Green Thumb Industries Inc.’s Request to Participate in a Hearing and
Notice of Appearance (Docket No. DEA-1362)**
Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Dear Administrator:

As DEA is aware, marijuana is currently categorized as a schedule I substance, making it subject to the most stringent controls under the Controlled Substances Act (“CSA”). At present, according to the CSA, schedule I substances have no accepted medical use and a high potential for abuse.¹ However, the country’s leading health agency, the Department of Health and Human Services (“HHS”), determined that marijuana (i) has a currently accepted medical use for treatment in the United States, (ii) has a low potential for abuse, (iii) does not belong in schedule I, and (iv) is more appropriately placed in schedule III.²

President Richard Nixon’s decision in 1970 to place marijuana in the most restrictive category was based not on science or logic, but on prejudicial partisan politics.³ At the same time, and notwithstanding the fact that they are the most widely used drugs in the country, Congress exempted alcohol and nicotine from the CSA.⁴ Nixon’s decision to place marijuana in schedule I followed a recommendation by a commission of scientists who argued that marijuana did not pose a danger to public health and should be decriminalized.⁵ The White House ignored the commission’s recommendation. A subsequent admission by President Nixon confirmed that marijuana was “not particularly dangerous.”⁶ Nixon’s decision fifty-four years ago led to the

¹ DEA, *Drug Scheduling*, <https://www.dea.gov/drug-information/drug-scheduling>.

² See Letter to Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (with enclosures) (Aug. 29, 2023), <https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf>.

³ Ernesto Londoño, *Nixon Started the War on Drugs. Privately, He Said Pot Was ‘Not Particularly Dangerous.’*, THE NEW YORK TIMES (Sept. 14, 2024), <https://www.nytimes.com/2024/09/14/us/nixon-marijuana-tapes.html>.

⁴ Nicole R. Ortiz & Charles V. Preuss, *Controlled Substance Act*, STATPEARLS (Feb. 9, 2024), <https://www.ncbi.nlm.nih.gov/books/NBK574544/>.

⁵ Londoño, *supra* note 3.

⁶ Londoño, *supra* note 3.

September 30, 2024

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stifling of important research and the unwarranted and unjust imprisonment of thousands of people, primarily people of color.

If marijuana did not belong in schedule I in 1970, it surely does not belong in schedule I today. Controlled substances in schedule I are deemed to be devoid of any medical utility. Controlled substances elsewhere on the schedule necessarily have been determined to have a “currently accepted medical use in treatment in the United States.” Over the past decade, thirty-eight state medical markets have opened, including in states where Green Thumb Industries Inc. (“GTI” or the “Company”) regularly operates. This is precisely the evidence upon which HHS relied in making its determination that marijuana has a currently accepted medical use in treatment in the United States. Our leading health agencies also found that marijuana has a lower potential for abuse than any drugs in schedule II, including fentanyl. DEA now has an opportunity to correct past mistakes, recognize HHS’s determination that marijuana has medical utility and a low potential for abuse, move beyond the stigma of the past, and refocus efforts on drugs that are actually harming the American public.⁷ Plainly, marijuana belongs in schedule III, IV, or V—or in the alternative should not be scheduled at all.

On May 21, 2024, DOJ issued a Notice of Proposed Rulemaking, entitled *Schedules of Controlled Substances: Rescheduling of Marijuana*. 89 Fed. Reg. 44,597 (May 21, 2024) (the “Proposed Rule”). The Proposed Rule noted that DEA may hold a hearing to “receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances.” *Id.* at 44,599 (cleaned up). In August 2024, DEA noticed such a hearing for December 2, 2024. *Notice of Hearing on Proposed Rulemaking*, 89 Fed. Reg. 70,148 (Aug. 29, 2024).⁸

Pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, GTI hereby submits, as an “interested person,” this Request to Participate in a Hearing and Notice of Appearance at the hearing set for December 2, 2024.⁹ This request to participate serves to inform DEA that GTI is an interested person and anticipates participating in the agency’s administrative hearing.¹⁰ This request also serves to inform DEA that the evidence to be offered by GTI will be competent, relevant, material, and not unduly repetitive. This request to participate is timely filed, as interested persons are required to submit a notice of their intent to participate on or before September 30, 2024.

⁷ Nat’l Inst. of Health, *Drug Overdose Deaths: Facts and Figures*, <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig2> (last accessed Sept. 23, 2024) (Click to expand “U.S. Overdose Deaths, Select Drugs or Drug Categories, 1999-2022”).

⁸ See C.F.R. § 1308.44(c) and § 1316.48.

⁹ If selected to participate, GTI will offer testimony from its Chief Executive Officer, founder, and Chairman, Ben Kovler, or its President, Anthony Georgiadis (or another C-Suite executive).

¹⁰ GTI is a member of the American Trade Association of Cannabis and Hemp (“ATACH”), which separately submitted a public comment on the Proposed Rule on behalf of its members, including GTI.

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I. GTI Is an Interested Person.

GTI is an interested person within the zone of interests and will be adversely affected or aggrieved by this proposed rule should the Administrator decide against a schedule III placement (or schedule IV or V) or if new DEA controls are implemented.¹¹ The schedule I classification of marijuana has been an impediment to GTI's growth and any new DEA controls would impact GTI's ability to operate responsibly, successfully, and profitably, thus affecting GTI's ability to properly serve its medical patients and other consumers. GTI has expertise in the medical marijuana markets in which it operates and thus can speak directly to marijuana's "medical use in treatment in the United States." As we explain in detail below, this expertise, as well as GTI's status as a successful and responsible multi-state marijuana operator, makes the Company uniquely qualified to participate in and inform the DEA's rulemaking process.

Given its history serving medical patients and customers in multiple markets across the United States, GTI has a unique perspective and is prepared to offer invaluable insights and assist DEA in building a comprehensive administrative record regarding (i) the practical consequences of rescheduling, including the economic impact of Section 280E of the Internal Revenue Code ("Section 280E") and its direct effect on public health and safety; (ii) the impact of new marijuana-specific DEA controls on GTI and its vendors, patients, and customers; and (iii) marijuana's currently accepted medical use in treatment in the states in which GTI is licensed to operate.

A. Practical Consequences of the Proposed Rule on GTI

DEA seeks comments on the "practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks." Proposed Rule at 44,621. GTI is prepared to provide testimony and documentary evidence on the implications of Section 280E on state-licensed businesses and the dire public health and safety consequences of a final rule keeping marijuana in schedule I or transferring it to schedule II. If DEA were to keep marijuana in schedule I (or move marijuana to schedule II), that decision would have detrimental impacts on GTI as well as on the public health and safety of American consumers nationwide.

Without a reclassification to schedule III, the future of the highly regulated state-legal marijuana marketplace (including GTI) is at risk—and public health and safety will suffer the consequences. A final rule reclassifying marijuana into schedule III would provide Section 280E tax relief to the state-regulated industry, allowing the industry to compete more effectively with the untaxed, unregulated marijuana marketplaces that are operating in interstate commerce.

The illicit marijuana market pays no taxes at all. Neither do many companies manufacturing intoxicating hemp-derived delta-9 products that test below 0.3% delta-9 THC on a dry weight basis and intoxicating hemp-derived delta-8 THC products, as they are not subject to Section 280E

¹¹ The "zone of interests" is defined as the "class or type of interests or concerns that a statute or constitutional guarantee is intended to regulate or protect." ZONE OF INTERESTS, Black's Law Dictionary (12th ed. 2024). "To have standing to challenge a ruling (esp. of an administrative agency), the plaintiff must show that the specific injury suffered comes within the zone of interests protected by the statute on which the ruling was based." *Id.*

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because they *could be* outside schedule I or II.¹² Competition from the unregulated illicit marijuana market and the unregulated intoxicating (arguably synthetic) hemp-derived marketplace has proven quite formidable, largely because both industries are selling untested intoxicating marijuana and hemp-derived products in interstate commerce without having to contend with stringent product testing, regulatory compliance costs, or the punitive tax effect of Section 280E. This is especially problematic. The state-legal marijuana marketplace protects patients and consumers through regulations that require strict packaging and labeling standards, testing protocols, dosage limits, and age verification, thereby shouldering costs that the intoxicating hemp industry and illicit marijuana markets shirk by operating without similar guardrails to protect American patients and consumers. Some bad actors in the hemp industry are even overtly marketing products to children by replicating common consumer brands that directly appeal to youth.¹³ The Food and Drug Administration (“FDA”) and Federal Trade Commission (“FTC”) have taken note and issued multiple warning letters, but the crisis persists.

There is only one solution: stop marijuana from being subjected to penalties associated with Section 280E. Without a reclassification of marijuana to schedule III, many state-legal marijuana companies will turn insolvent and be forced to shut down while the two competing unregulated marijuana industries flourish, jeopardizing patient and consumer public health and safety. Rescheduling marijuana to schedule III will remove the most significant impediment to profitability currently imposed on the state-regulated marijuana industry. It is not just public health and safety that would benefit from this change. Tax savings attributable to relief from Section 280E could increase employee wages (especially retail employee wages, which are currently not deductible), employee benefits, and job creation as well as reignite investment into product development, clinical research, and the communities in which state-regulated companies operate, including the fourteen states in which GTI is licensed to operate.¹⁴ If regulated companies such as GTI survive, patients and consumers will benefit from having access to safe, tested, age-verified, regulated marijuana products.

GTI has extensive knowledge and experience regarding the practical effects of Section 280E on the state-legal, regulated marijuana marketplace, and is particularly well-suited to offer testimony on this subject, as it is licensed to operate in fourteen states. GTI currently suffers immense tax consequences because Section 280E allows the Company to deduct only expenses directly related to sales of product, a restriction to the marijuana industry. This is unique to the cannabis industry and differs from normal businesses that, for tax purposes, are allowed to deduct all expenses

¹² Patrick Oglesby, *Will Congress’s Marijuana Tax Die an Administrative Death?*, 184 TAX NOTES 2277 (Sept. 16, 2024), <https://www.taxnotes.com/tax-notes-federal/exemptions-and-deductions/will-congresss-marijuana-tax-die-administrative-death/2024/09/16/7151m>.

¹³ Press Release, Federal Trade Commission, *FTC and FDA Send Second Set of Cease-and-Desist Letters to Companies Selling Products Containing Delta-8 THC in Packaging Designed to Look Like Children’s Snacks* (Jul. 16, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-fda-send-second-set-cease-desist-letters-companies-selling-products-containing-delta-8-thc>.

¹⁴ Andrew Kline & Sammy Markland, *State-Regulated Cannabis Can Thrive Without Section 280E*, LAW360 (May 14, 2024), <https://www.law360.com/articles/1835160/>.

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incurred. This results in permanent differences between ordinary and necessary business expenses deemed non-allowable under Section 280E. Since 2019, the Company has paid more than \$500 million in income taxes on approximately \$500 million of pre-tax income in the same time period. The impact of Section 280E has required the Company to pay approximately an additional \$200 million in income taxes during this time, and GTI would see its tax burden get cut in half if Section 280E did not apply.

B. Impact of New Marijuana-Specific Controls on GTI

DEA is considering marijuana-specific controls associated with international treaty obligations. Proposed Rule at 44,599. The Office of Legal Counsel (“OLC”) concluded that “additional controls pursuant to the CSA’s regulatory authorities” may be necessary. OLC, *Questions Related to the Potential Rescheduling of Marijuana*, at 4 (Apr. 11, 2024).¹⁵ Among other things, “if marijuana is transferred into schedule III, DEA will continue to have authority to maintain its existing regulatory scheme . . . governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marijuana.” Proposed Rule at 44,620. *See also id.* at 44,621 (“If marijuana is transferred to schedule III, the regulatory controls applicable to schedule III-controlled substances would apply, as appropriate.”). DEA will presumably consider any such updated controls during this administrative hearing. GTI is well positioned to present evidence and offer testimony regarding the potential impact of any new and currently unknown DEA controls on GTI and other similarly situated regulated businesses. GTI currently adheres to regulations in fourteen different states that adequately protect patients and customers and can speak to its experience complying with these regulations, many of which may be duplicative of DEA controls being contemplated.

The Proposed Rule and any new DEA controls would directly impact GTI. GTI may be subject to new DEA registration requirements regarding the manufacturing of marijuana or marijuana products, as well as any other regulatory controls applicable to schedule III substances. New DEA controls would adversely impact how GTI operates and would impose new and potentially substantial costs. For instance, DEA rules could require that the agency play a role in the handling of final products, including burdensome paperwork, storage requirements, and methods of destruction, which is currently regulated directly by the states with marijuana-regulated programs.

GTI’s laboratory partners may also be subject to new DEA registration requirements and controls applicable to schedule III substances. *See* Proposed Rule at 44,620–21. Testing laboratories are not currently required to hold a DEA license under state-regulated programs. Requiring them to register with DEA would be costly and arduous and any such increased costs may ultimately be borne by patients and consumers. GTI’s laboratory partners may also be subject to such new controls, costing GTI monies that have not been budgeted for or contemplated in Company forecasts. Compliance with these potential requirements could generate increased staffing costs, expensive modifications to laboratory facilities, and contracting with DEA-licensed disposal firms. Requiring laboratories to become DEA-licensed could also prevent them from accepting products

¹⁵ This OLC opinion is attached as Exhibit A.

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from the state-licensed marijuana market as well as the hemp market, rendering their businesses obsolete.

Similarly, under the status quo, DEA does not enforce its regulatory requirements obligating marijuana labs to accept marijuana sample material only from other DEA-registered entities. This non-enforcement policy is essential to state-licensed labs that service GTI and others in the marijuana industry because most of the entities submitting samples to marijuana labs nationwide are not themselves registered with DEA. Thus, GTI and its lab partners are adversely impacted by the uncertainty surrounding the promulgation of potential new DEA controls or the enforcement of existing rules that currently remain unenforced. Not only are GTI and its partner laboratories within the zone of interests, but they are thus also aggrieved because of the uncertainties surrounding new or updated DEA controls.

C. Impact of a Schedule I Designation on GTI, and GTI's Experience in Recognizing Marijuana's Currently Accepted Medical Use in Treatment in the United States

The Proposed Rule recognizes that marijuana has a currently accepted medical use in treatment in the United States. As detailed in the Proposed Rule, HHS conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III. 89 Fed. Reg. at 44,600. Specifically, HHS concluded that marijuana has a currently accepted medical use in treatment in the United States. *Id.* Thirty-eight states, the District of Columbia, and four U.S. territories have legalized the use of medical marijuana, allowing the use of the substance to treat certain health conditions, including chronic pain. *Id.*

GTI has significant interest in making certain that the administrative hearing includes the most current and most accurate scientific knowledge regarding the medical use of marijuana. GTI has first-hand experience in multiple medical markets and could offer insight into how doctors are recommending marijuana to treat various ailments in the states in which GTI is licensed to operate. GTI has witnessed firsthand the transformational powers of medical marijuana for its patients. With well over one million transactions informing operations in fourteen medical markets, GTI is equipped with patient testimonials that directly validate marijuana's "medical use in treatment in the United States." From opioid alternatives for chronic pain to relief from the challenges posed by other ailments, the nearly 200,000 medical patients served by GTI across fourteen states demonstrate that GTI's tested medical marijuana products have been treating a variety of ailments in numerous state markets for nearly a decade. A sample of those testimonials follows:

- Nick is a medical patient at Rise Cranberry, a GTI-owned and operated dispensary. After falling off a roof, Nick endured multiple severe injuries, including facial trauma and a shattered wrist that both required reconstructive surgery, several broken ribs, and a collapsed lung. The severity of these injuries left him facing not only immense physical pain but also a difficult path to healing. Initially, Nick relied on strong prescription pain medications to manage the intense pain. However, he was determined to find a healthier

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and more sustainable way to recover without becoming dependent on opioids. That is when Nick turned to medical marijuana. Not only has marijuana helped him to regain control over his pain, but it has also allowed him to improve his overall quality of life during his recovery. His journey is a powerful testament to the therapeutic potential of medical marijuana.

- Apollo is a patient within GTI's medical marijuana program. He uses medical marijuana as a cancer survivor. When he was 17, Apollo was diagnosed with thyroid cancer. He was a senior in high school when a malignant tumor was found to have consumed the right half of his thyroid gland. Upon that discovery, he underwent a thyroidectomy. After having his thyroid removed, Apollo endured two rounds of radioactive iodine treatment. Now as a 25-year-old cancer survivor, he manages many chronic conditions that are a result of living without a thyroid. Apollo uses medical marijuana because it helps to reduce the daily aches and pains. Additionally, because the regulated market has consumer protections in place, Apollo knows that his state-regulated products are safe and will not jeopardize his overall health with contaminants that are commonly found in illicit market products.
- Tim is a 61-year-old survivor of a brain tumor that was removed when he was 32 years old. He has used marijuana to quiet his "survivor syndrome" and to relieve chronic pain from taking hormone replacement medications for the past 29 years. Tim acquired his marijuana on the illicit market from 1994 until 2018—when he received his medical marijuana patient card in Pennsylvania. Buying his medicine from the illicit market for 25 years caused him concern about being arrested and losing his job, house, and family. Now, Tim discloses to his employer that he has a medical card, without fear of retribution. And he is getting the medicine that he needs from a safe distributor.

GTI executives are prepared to offer testimony about medical use in treatment in the United States through their patients' stories in fourteen state medical markets. This testimony would be direct evidence that marijuana medicine is providing wellness for those people suffering from medical conditions, and that there is in fact "medical use in treatment in the United States" for patients using marijuana to treat chronic pain and other ailments.

II. GTI Has Administrative Standing to Participate in a Hearing.

Under the Administrative Procedure Act ("APA"), 5 U.S.C. § 555(b), "an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding," "[s]o far as the orderly conduct of public business permits." DEA regulations accordingly provide that an "interested person" may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c). DEA regulations, in turn, define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule

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issuable pursuant to [21 U.S.C. § 811].” 21 C.F.R. § 1300.01(b).¹⁶ GTI is an “interested person,” and therefore qualifies to participate in the upcoming hearing.

As the discussion that follows demonstrates, GTI qualifies as an “interested person” for two reasons. First, GTI falls within the CSA’s zone of interests. Second, GTI will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized, particularly if DEA decides that marijuana belongs in schedule I or II or new DEA controls are implemented.

First, GTI falls within the CSA’s “zone of interests.” In May 2022, a DEA Administrative Law Judge (“ALJ”) concluded that the test for “adversely affected or aggrieved”—and, consequently, “interested person”—was satisfied when the person fell within the “zone of interests” to be regulated by the CSA. ALJ Order at 10. The Supreme Court of the United States has explained that the “zone of interests” test is “not meant to be especially demanding” given Congress’s intent to “make agency action presumptively reviewable.” *Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209, 225 (2012) (citation omitted).

A party falls “within the zone of interests,” the ALJ explained, “if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question.” ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). With regard to the CSA, the Supreme Court has noted that the statute was enacted with “the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Oregon*, 546 U.S. 243, 250 (2005).

GTI falls within the CSA’s zone of interests. GTI is regulated by the Proposed Rule and the CSA. Each day, GTI produces high-quality, heavily regulated, and tested products in compliance with various state-regulated marijuana programs and actively fights against the perils of the illicit marketplace, unregulated hemp-derived intoxicants, and the illegal trafficking in fentanyl and other opioid derivatives. GTI may also see new marijuana-specific controls related to marijuana-related activities under the Proposed Rule. Proposed Rule at 44,620–21.

Second, GTI would be adversely affected or aggrieved by the Proposed Rule, if finalized to place marijuana in schedule I or schedule II, and therefore qualifies as an interested person. GTI is prepared to present evidence on these facts at a hearing.

DEA has previously argued that participation in an administrative rulemaking hearing under the CSA requires the equivalent of Article III standing. *See In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022) at 4 (“ALJ Order”).¹⁷ An ALJ has soundly rejected this argument, concluding instead that it is sufficient that a person falls within the CSA’s “zone of interests.” *See id.* at 5–6. Thus, GTI need only show administrative standing, rather than Article III standing, to participate in this

¹⁶ Pursuant to 21 C.F.R. § 1300.01(b), “person” includes “any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.”

¹⁷ The ALJ Order is attached here as Exhibit B.

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administrative proceeding. *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (discussing a lower threshold required for “administrative standing” compared to Article III standing). But regardless, for all the reasons described herein, GTI has standing under both standards.¹⁸

III. There Is No Reason to Deny GTI’s Request to Participate at the Upcoming Hearing.

None of the reasons courts have cited to deny a movant’s participation in an administrative proceeding apply here. *See Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). Collecting cases, the D.C. Circuit noted that courts had denied participation when (i) other parties to the proceeding were deemed to adequately represent the would-be participant’s viewpoint; (ii) participation would broaden unduly the issues considered or obstruct or overburden the proceedings; or (iii) participation would fail to assist the agency’s decision-making. *Id.*

First, as explained above, no other participant in the rulemaking would adequately represent GTI’s viewpoint.¹⁹ GTI also has interests in the rulemaking proceedings distinct from those of DEA. As one of the largest companies in the marijuana industry, GTI can speak to (i) the practical consequences of rescheduling across the marijuana supply chain, including the economic impact of Section 280E and its direct effect on public health and safety; (ii) the impact of new marijuana-specific DEA controls on GTI and its vendors and customers; and (iii) marijuana’s currently accepted medical use in treatment in the states in which GTI operates, among other topics. Second, GTI’s participation would not obstruct proceedings or unreasonably broaden the issues under consideration in the Proposed Rule. DEA has sought information on the practical consequences of rescheduling, and GTI is prepared to provide that perspective. Third, GTI’s participation would benefit the agency’s decision-making process.

¹⁸ The fact that GTI engages in business activities that are impermissible under current federal drug scheduling only heightens its interest in participating in the hearing. In the context of federal litigation, which employs the more onerous Article III standing requirements, only parties that are impacted by, or that violate, a specific state or federal law may challenge that law. *See Gonzalez v. Raich*, 545 U.S. 1 (2005) (individuals cultivating and ingesting marijuana in violation of Controlled Substances Act sought injunctive and declaratory relief prohibiting DEA from enforcing the Act); *see also, e.g., Lawrence v. Texas*, 539 U.S. 558, 562 (2003) (two men arrested for engaging in sexual act successfully challenged Texas law prohibiting same-sex intercourse); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (physicians that provided contraceptives in violation of Connecticut law had standing to challenge that law on behalf of themselves and their patients); *Korematsu v. United States*, 319 U.S. 432, 434 (1943) (man of Japanese ancestry who refused to relocate to internment camp challenged federal law requiring removal of people of Japanese ancestry). Indeed, only a few months ago, a federal court expressly concluded that companies that cultivate marijuana in violation of the CSA have Article III standing to challenge the constitutionality of the CSA. *Canna Provisions, Inc. v. Garland*, No. CV 23-30113-MGM, 2024 WL 3269534, at *3–*6 (D. Mass. July 1, 2024). With the rulemaking, DEA is expressly seeking to reschedule marijuana to schedule III, and GTI is directly affected by this proposed rule.

¹⁹ While this filing is made without knowledge of other participants in the potential ALJ hearing, GTI provides a unique perspective that would not be cumulative to or adequately represented by other participants at the upcoming hearing regarding the Proposed Rule.

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For all these reasons, GTI hereby requests the ability to participate in DEA's administrative hearing on December 2, 2024.

All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully submitted,



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Enclosures

- Exhibit A: OLC, *Questions Related to the Potential Rescheduling of Marijuana* (Apr. 11, 2024)
- Exhibit B: *In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022)

Exhibit A

Questions Related to the Potential Rescheduling of Marijuana

The approach that the Drug Enforcement Administration currently uses to determine whether a drug has a “currently accepted medical use in treatment in the United States” under the Controlled Substances Act is impermissibly narrow. An alternative, two-part inquiry proposed by the Department of Health and Human Services is sufficient to establish that a drug has a “currently accepted medical use” even if the drug would not satisfy DEA’s current approach.

Under 21 U.S.C. § 811(b), a recommendation by HHS that a drug has or lacks a “currently acceptable medical use” does not bind DEA. In contrast, the scientific and medical determinations that underlie HHS’s “currently acceptable medical use” recommendation are binding on DEA, but only until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS’s determinations no longer bind DEA, but DEA must continue to accord HHS’s scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS’s findings at any point in the process.

Neither the Single Convention on Narcotic Drugs nor the CSA requires marijuana to be placed into Schedule I or II of the CSA. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific restrictions that follow from a drug’s placement on a particular schedule. As a result, DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA’s regulatory authorities.

April 11, 2024

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Controlled Substances Act (“CSA”)¹ imposes a unified framework for controlling drugs and other substances that are found to pose a risk of abuse.² In doing so, it seeks to balance several, often competing, interests. These interests include ensuring the availability of drugs that “have a

¹ In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, the provisions of which are codified at Chapter 13 of Title 21 of the U.S. Code. The Act comprised several titles, including Title II, which it called the Controlled Substances Act, and Title III, which it called the Controlled Substances Import and Export Act. For ease of reference, we refer to the entire 1970 law as the CSA.

² The CSA applies to both drugs and “other substance[s]” that have been controlled. See 21 U.S.C. § 802(6). For ease of reference, we use the term “drug” to refer to both.

useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people”; preventing the “illegal importation, manufacture, distribution, and possession and improper use of controlled substances [that] have a substantial and detrimental effect on the health and general welfare of the American people”; and ensuring that the United States complies with “international conventions designed to establish effective control over international and domestic traffic in controlled substances.” 21 U.S.C. § 801(1), (2), (7).

The CSA balances these purposes by placing each drug warranting control into one of five “schedules,” with drugs in Schedule I subject to the strictest regulatory and criminal provisions, and drugs in Schedule V subject to the least strict. *See generally* 21 U.S.C. §§ 821–832, 841–865, 951–971. The CSA further authorizes the Attorney General to add, transfer, and remove drugs from the schedules using formal rulemaking procedures, *see id.* §§ 811, 812, and otherwise grants the Attorney General broad authority to take regulatory action consistent with the Act, *see, e.g., id.* §§ 821, 871(b). The Attorney General has in turn generally delegated these functions to the Administrator of the Drug Enforcement Administration (“DEA”). 28 C.F.R. § 0.100(b).

Marijuana has been a Schedule I drug since Congress enacted the CSA. *See* 21 U.S.C. § 812(c). To reschedule marijuana from Schedule I, DEA would need to determine, among other things, that the drug has a “currently accepted medical use in treatment in the United States” (“CAMU”). *Id.* § 812(b). Since 1992, however, DEA has determined that a drug has a CAMU only if either the Food and Drug Administration (“FDA”) has approved the drug for marketing in interstate commerce under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, or the drug meets a five-part test that tracks the “core standards developed under the FDCA.” 57 Fed. Reg. 10,499, 10,503–04, 10,506 (Mar. 26, 1992). And because FDA has not approved marijuana and DEA has determined that marijuana does not meet its five-part test, DEA has repeatedly rejected petitions to move marijuana to a less restrictive schedule.

On October 6, 2022, President Biden asked the Secretary of Health and Human Services (“Secretary”) and the Attorney General to initiate an “administrative process to review expeditiously how marijuana is scheduled under federal law.” *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/>

statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform. The CSA requires the Secretary to provide certain recommendations before the initiation of proceedings to schedule or reschedule a drug, and the statute provides that the Secretary's recommendations "shall be binding" as to certain "scientific and medical matters." 21 U.S.C. § 811(b).

Consistent with this requirement, in 2023, the Department of Health and Human Services ("HHS") recommended that DEA reschedule marijuana to Schedule III. *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023). HHS concluded that, regardless of whether a drug was approved by FDA or satisfied DEA's five-part test, the drug could have a CAMU if it satisfied a new, two-part inquiry. Part 1 of that inquiry asks whether licensed health care providers have "widespread current experience with medical use" of the drug "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine." Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, *Re: Part 1 Analysis* at 1 (July 17, 2023) ("HHS Part 1 Analysis Memo"). If so, Part 2 of the inquiry asks whether there is "some credible scientific support for at least one of the medical uses." *Id.* at 2.

Against this backdrop, you have asked us three questions:³

- (1) If a drug satisfies the two-part inquiry employed by HHS, does that establish a currently accepted medical use under the statute even if the drug has not been approved by FDA and even if the drug does not satisfy DEA's five-part test?
- (2) To what extent do the "scientific and medical matters" referenced in 21 U.S.C. § 811(b), which are binding upon the Attorney General,

³ This opinion memorializes advice we provided you on February 16, 2024. To aid our analysis, we solicited and received written views from HHS and DEA on all three questions and from the State Department on the third question. *See* Memorandum for the Office of Legal Counsel from DEA (Jan. 30, 2024) ("DEA Response"); Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel R. Bagenstos, General Counsel, HHS, *Re: OLC's Request for Views on Issues Related to the Scheduling of Marijuana Under the Controlled Substances Act* (Jan. 29, 2024) ("HHS Response"); Single Convention Requirements for Cannabis and Scheduling Under the Controlled Substances Act (Feb. 12, 2024) ("State Response").

include the Secretary's evaluation of a drug's currently accepted medical use or any scientific and medical considerations involved in that evaluation?

(3) Does the CSA, including the requirement that the Attorney General control drugs "under the schedule he deems most appropriate to carry out" the United States' "obligations under international treaties, conventions, or protocols in effect on October 27, 1970," *id.* § 811(d)(1), require DEA to place marijuana in either Schedule I or Schedule II to comply with the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407 ("Single Convention")?

As explained in more detail below, we conclude, first, that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test.

Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA. We also conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

Third, we conclude that neither the Single Convention nor the CSA requires DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific controls that follow from a drug's placement on a particular schedule. As a result, we conclude that DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA's regulatory authorities.

I.

A.

Sections 811 and 812 of the CSA set forth the procedures and standards the Attorney General (and thus DEA) must follow to add a drug to a schedule, transfer a drug between schedules, or remove a drug from the schedules of control. Section 811(a) authorizes the Attorney General to add or transfer a drug to, or remove a drug from, a schedule by issuing a rule “made on the record after opportunity for a hearing” pursuant to the formal rulemaking procedures of the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 553(c), 556, 557. In promulgating such rules, the Attorney General is required to make particular findings, based on substantial evidence, that correspond to the schedule in which the drug is to be placed. 21 U.S.C. §§ 811(a)(1)(A)–(B), 812(b); *see also id.* § 811(b); 5 U.S.C. § 556(d).

Section 812(b) lists the findings the Attorney General must make to place a drug in a particular schedule, with the findings varying by schedule. For example, the Attorney General may place a drug in Schedule I only if the Attorney General finds that the drug “has a high potential for abuse,” 21 U.S.C. § 812(b)(1)(A); “has no currently accepted medical use in treatment in the United States,” *id.* § 812(b)(1)(B); and “[t]here is a lack of accepted safety for use” of the drug “under medical supervision,” *id.* § 812(b)(1)(C). To place drugs in other schedules, the Attorney General must similarly make three findings, except that drugs on the other schedules must have a CAMU (or, in the case of Schedule II drugs, a CAMU with “severe restrictions”). *Id.* § 812(b)(2)(B), (b)(3)(B), (b)(4)(B), (b)(5)(B). Drugs are to be placed in less restrictive schedules as their potential for abuse and likelihood of leading to physiological or physical dependence declines. *Id.* § 812(b)(2)–(5). In the course of making these findings, section 811(c) requires the Attorney General to consider eight medical, scientific, and law-enforcement factors regarding the drug:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.

- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c).

Although section 811 provides that the Attorney General will issue the final rule to schedule a drug, *see id.* § 811(a), the CSA also assigns a significant role in scheduling decisions to the Secretary. Section 811(b) requires the Attorney General, before initiating a rulemaking proceeding to schedule or reschedule a drug, to request both a scientific and medical evaluation of the drug from the Secretary and the Secretary's recommendation as to the schedule, if any, in which the drug should be placed. The Secretary's recommendations "shall be binding on the Attorney General as to such scientific and medical matters" and the Attorney General is prohibited from controlling a drug if the Secretary recommends that it not be controlled. *Id.* § 811(b). After receiving the views of the Secretary, the Attorney General must initiate rulemaking proceedings if there is sufficient evidence to do so. *See id.*

The legislative history of section 811(b) indicates that its purpose was to place scientific and medical judgments in the hands of the Secretary. The report of the House Committee on Interstate and Foreign Commerce explains that "[c]onsiderable controversy arose" during the drafting process over the scheduling provisions of the bill, in particular "with respect to the proper role of the Attorney General and the Secretary of Health, Education, and Welfare [(‘HEW’)]⁴ in making determinations concerning which drugs should be controlled." H.R. Rep. No. 91-1444, at 22 (1970).

⁴ In 1979, Congress created the Department of Education and changed the name of the Department of Health, Education, and Welfare to the Department of Health and Human Services. Department of Education Organization Act, Pub. L. No. 96-88, §§ 201, 509, 93 Stat. 668, 671, 695 (1979).

This controversy appears to have stemmed from the fact that the version of the CSA that passed the Senate vested full decisionmaking authority regarding scheduling in the Attorney General alone and required only that the Attorney General obtain the “advice” of the Secretary in connection with scheduling decisions. S. 3246, 91st Cong. § 201(a) (1970); *see* 116 Cong. Rec. 1671, 1672 (1970). During the House’s consideration of the bill, Members of Congress, HEW officials, and scientific and medical professionals raised concerns over the dominant role the Senate bill assigned to the Attorney General, arguing that scheduling decisions largely require scientific and medical expertise and that HEW, not the Department of Justice, had this expertise. *See, e.g., Drug Abuse Control Amendments—1970: Hearings Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Commerce*, 91st Cong. 102–04, 194–95, 199, 550, 557, 580–81 (1970) (“House Hearing”).

Reflecting these concerns, the House version of the bill, H.R. 18583, 91st Cong. (1970), made several changes to what is now 21 U.S.C. § 811(b) that expanded the role of the Secretary and eventually became law. The requirement that the Attorney General obtain “advice” was changed to an obligation to obtain “recommendations” that bound the Attorney General with respect to scientific and medical matters. H.R. 18583, § 201(b). The House bill also added a requirement that the Secretary give a recommendation regarding the schedule in which the drug should be placed and provided that the Attorney General could not control a drug that the Secretary recommended not be controlled. *Id.*

B.

As noted above, Congress classified marijuana as a Schedule I drug when it enacted the CSA in 1970. *See* 21 U.S.C. § 812(c). Shortly thereafter, several organizations petitioned to move marijuana from Schedule I to Schedule V. *See* 37 Fed. Reg. 18,097 (Sept. 7, 1972). The petition was denied three times, but each time on review the United States Court of Appeals for the District of Columbia Circuit remanded for further analysis. *See Nat’l Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654, 661 (D.C. Cir. 1974); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977) (“NORML II”); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, No. 79-1660, 1980 U.S. App. LEXIS 13099, at *1 (D.C. Cir. Oct. 16, 1980) (*per curiam*).

After the third remand, DEA denied the rescheduling petition once more, concluding that marijuana did not have a CAMU. *See* 54 Fed. Reg. 53,767, 53,767, 53,783–84 (Dec. 29, 1989). In reaching that conclusion, DEA relied on an eight-part test for determining whether a drug had a CAMU that included the following three factors: whether the drug was generally available; whether its use was generally recognized in various medical reference works; and whether its use was recognized by “a substantial segment of the medical practitioners in the United States.” *Id.* at 53,783. As before, the petitioners sought review and the D.C. Circuit remanded the case to DEA, concluding that these three factors were arbitrary and capricious because they would be “logically impossible” for drugs in Schedule I to satisfy. *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937, 940 (D.C. Cir. 1991) (“*ACT I*”). But the court held that DEA’s interpretation of the statutory phrase “currently accepted medical use” was “in the main acceptable,” and rejected petitioners’ principal argument that DEA’s interpretation unreasonably relied upon “the absence of demonstrated scientific evidence that the drug is medically useful and safe.” *Id.* at 937, 939. In particular, the court noted that the petitioners had presented only “anecdotal evidence” that “a number of physicians believe marijuana is medically useful.” *Id.* at 939.

On remand a fourth time, DEA again denied the petition, again finding that marijuana did not have a CAMU. 57 Fed. Reg. at 10,499. DEA stated that a drug would have a CAMU if it had been approved by FDA under its “New Drug Application” process or if the drug met the criteria to be recognized by FDA as “Generally Recognized As Safe and Effective.” *Id.* at 10,503 (citing 21 U.S.C. §§ 321(p), 355). In addition, DEA concluded that a drug would have a CAMU if it satisfied a new, five-part test (a revised version of DEA’s previous eight-part test that the D.C. Circuit considered in *ACT I*). *Id.* at 10,504. Under DEA’s new test, a drug has a CAMU if the following elements are satisfied:

- (1) the drug’s chemistry is known and reproducible;
- (2) there are adequate safety studies;
- (3) there are adequate and well-controlled studies proving efficacy;
- (4) the drug is accepted by qualified experts; and
- (5) scientific evidence about the drug is widely available.

Id. at 10,503–06. All five parts were based on the “core FDCA standards for acceptance of drugs for medical use,” and four were expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval. *Id.* at 10,504–05 (citing 21 U.S.C. §§ 321(p), (w), 355(d); and 21 C.F.R. §§ 314.103(c)(3), 314.50(d)(1), 314.125(b), 314.126). DEA concluded that marijuana did not meet any of these criteria and accordingly denied the request to remove marijuana from Schedule I. *Id.* at 10,507–08.

This time the D.C. Circuit upheld DEA’s decision. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994) (“*ACT I*”). It rejected the petitioners’ “central claim” that DEA’s order rested on an “unreasonable interpretation of the statute.” *Id.* The court noted that it had already concluded in *ACT I* that DEA’s interpretation of the CSA was generally reasonable, and it refused to reconsider that determination. *Id.* at 1134. It further reasoned that none of the criteria in DEA’s new five-part test were “impossible for a Schedule I drug to meet” and that DEA had “corrected the flaws [the court] identified in” *ACT I*. *Id.* at 1135.

Since *ACT II*, DEA has denied several petitions that sought rescheduling of marijuana after applying its five-part test and concluding that marijuana did not have a CAMU. *See, e.g.*, 66 Fed. Reg. 20,038, 20,038 (Apr. 18, 2001); 76 Fed. Reg. 40,552, 40,552 (July 8, 2011); 81 Fed. Reg. 53,688, 53,688 (Aug. 12, 2016); 81 Fed. Reg. 53,767, 53,767 (Aug. 12, 2016). Efforts to challenge these denials in court have proven unsuccessful. *See Ams. for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013); *Krumm v. DEA*, 739 F. App’x 655 (D.C. Cir. 2018). In recent years, however, several jurists have raised serious concerns about DEA’s conclusion that marijuana does not have a CAMU. *See United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016); *United States v. Amalfi*, 47 F.4th 114, 125 (2d Cir. 2022); *Sisley v. DEA*, 11 F.4th 1029, 1036 (9th Cir. 2021) (Watford, J., concurring).

C.

Since 1996, 38 States, the District of Columbia, and four federal territories have legalized the use of medical marijuana. *See* HHS Part 1 Analysis Memo at 4. These laws typically allow the cultivation, sale, and use of marijuana by patients (or their caregivers) whose health care practitioners have recommended that they use marijuana to treat certain, specified

conditions. *See, e.g.*, Ohio Rev. Code §§ 3796.01(A)(6)(a)–(v), 3796.08(A); N.Y. Cannabis Law §§ 3(18), 30, 31; N.M. Stat. §§ 26-2B-3(F)(1)–(23), 26-2B-3(N), 26-2B-4(A). Conditions can be added to, or removed from, the list of illnesses that may be treated with marijuana, often by (or at the recommendation of) a state’s public health authorities or special boards convened to consider such matters. *See, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c); 410 Ill. Comp. Stat. §§ 130/10(h)(2), 130/45; Or. Admin. Rule 333-008-0090. In each fiscal year since 2015, Congress has also adopted an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *E.g.*, Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, § 531, 138 Stat. 25; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 531, 136 Stat. 4459, 4561 (2022); *see* Cong. Rsch. Serv., R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap* at 26 & n.159 (updated Apr. 7, 2022) (collecting laws).

On October 6, 2022, as noted above, President Biden asked the Secretary and the Attorney General to review how marijuana is scheduled under federal law. As part of its analysis in response to this request, HHS considered whether DEA’s test for determining if a drug has a CAMU was consistent with the text of the CSA. HHS Response at 5–6. HHS agreed that if a drug met the requirements for FDA approval or DEA’s five-part test, the drug would have a CAMU. *Id.* at 8. But it concluded that it would be inconsistent with the text and purpose of the CSA for those standards to be the “sole basis for determining whether a substance has a [CAMU].” *Id.* at 7.

HHS’s analysis instead relied on an additional, two-part inquiry for considering whether a drug has a CAMU. Part 1 of HHS’s inquiry focuses on the extent and nature of medical use. It asks whether there is “widespread current experience with medical use of the substance in the United States by licensed health care practitioners . . . operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part 1 Analysis Memo at 1. HHS further identifies several factors to consider in undertaking this analysis, none being dispositive on its own—specifically, (1) “[w]hether a substantial number of licensed health care practitioners

have gained clinical experience with at least one specific medical use of the substance under existing and implemented state-authorized programs,” *id.* at 3; (2) “[w]hether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance,” *id.*; and (3) “[w]hether licensed health care practitioners’ clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer term toxicities and potential harms of the substance when used under medical supervision,” *id.* at 5.

Part 2 of HHS’s test focuses on the scientific basis for any identified medical use. It asks whether there is “some credible scientific support for at least one medical use of the substance for which Part 1 is met.” *Id.* at 2. According to HHS, although again not dispositive, factors that count in favor of the conclusion that some credible scientific support exists include (1) whether “favorable clinical studies of the medical use” of the drug, although not FDA approval-level studies, “have been published in peer-reviewed journals” and (2) whether “[q]ualified expert organizations (e.g., academic or professional societies, government agencies) have opined in favor of the medical use or provided guidance to practitioners on the medical use.” Ctr. for Drug Evaluation & Rsch., FDA, *Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act* at 4 (Aug. 28, 2023) (“HHS Part 2 Analysis Memo”). By contrast, factors weighing against the conclusion that such credible scientific support exists include (1) whether “data or information indicates that medical use of the substance poses unacceptably high safety risks for the likely patient population, e.g., due to toxicity concerns”; (2) whether “clinical studies with negative efficacy findings for the medical use have been published in peer reviewed journals”; and (3) whether “qualified expert organizations (e.g., academic or professional societies, government agencies) have recommended against the medical use of the substance.” *Id.* at 4–5.

Applying this two-part inquiry, HHS concluded that marijuana has a CAMU. *Id.* It found that Part 1 of its inquiry was satisfied because more than 30,000 licensed health care practitioners across 43 jurisdictions are authorized to recommend the use of marijuana for more than six million registered patients for at least 15 medical conditions. HHS Part 1 Analysis Memo at 1. HHS also found that Part 2 of its inquiry was satisfied. *See*

HHS Part 2 Analysis Memo at 7. Although noting that no professional medical organization currently recommends use of marijuana (and that one recommends against its use), HHS concluded after reviewing several studies that there was some credible scientific support that marijuana could be used to effectively treat pain, anorexia, and nausea and vomiting and that using medical marijuana to treat these conditions did not pose “unacceptably high safety risks.” *Id.* at 7. Consistent with this conclusion, and in light of other findings it made, HHS recommended to DEA that marijuana be placed in Schedule III of the CSA.

II.

As discussed above, DEA currently concludes that a drug has a CAMU only if FDA has approved the drug under the FDCA or the drug meets DEA’s five-part test. 57 Fed. Reg. at 10,505–06. HHS agrees with DEA that FDA approval and DEA’s five-part test are sufficient to establish that a drug has a CAMU, *see* HHS Response at 8, and we also agree. To receive FDA approval, a drug must satisfy “rigorous testing and safety reviews” showing that the drug is “both safe and effective.” *Sadoz Inc. v. Becerra*, 57 F.4th 272, 282 (D.C. Cir. 2023). And the entire purpose of FDA’s rigorous approval process is to identify drugs that can be safely and effectively used to treat medical conditions. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133–34 (2000). It would thus make no sense to keep a drug that has met—or could meet—FDA’s standards on Schedule I, which would prevent the drug from being used to treat medical conditions. *See* 21 U.S.C. §§ 829, 841–43.

HHS argues, however, that DEA’s approach to CAMU is impermissibly narrow and that HHS’s two-part inquiry is a permissible way to establish that a drug has a CAMU. You have asked whether, if a drug satisfies the two-part inquiry employed by HHS, that establishes that the drug has a CAMU regardless of whether the drug has been approved by FDA or satisfies DEA’s five-part test. For the reasons that follow, we agree with HHS and conclude that limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA’s five-part test is an impermissibly narrow interpretation of section 812(b) and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU.

A.

Section 812(b) requires the Attorney General (and thus DEA), in making scheduling decisions under the CSA, to determine whether a drug has a “currently accepted medical use in treatment in the United States.” It is hard to square DEA’s exclusive reliance on FDA approval and its five-part test with this language.

To begin, DEA’s approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard. At the time the CSA was adopted (and as is still true today) the word “accepted” meant “widely used or found” or “generally approved.” *Accepted*, Webster’s Third New International Dictionary 11 (1971); *see also Accepted*, The American Heritage Dictionary of the English Language 8 (1970) (“Generally approved, believed, or recognized.”); *Accepted*, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/accepted> (last visited Apr. 2, 2024) (defining “accepted” to mean “regarded favorably” or “generally approved or used”). And the focus on “medical use” suggests that the relevant inquiry is whether the medical community has accepted that a drug has a “use in treatment.” 21 U.S.C. § 812(b)(1)(B).

Any examination of whether the medical community “accept[s]” that a drug has a “use in treatment,” *id.*, naturally requires an examination of what licensed health care practitioners are actually doing. Practitioners treat patients, after all, and their treatment decisions and clinical experience with a drug (where such experience exists) provide important evidence in determining whether a medical use is accepted. Moreover, an understanding of what the medical community accepts would also naturally require consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners. As the Supreme Court has noted, the CSA “presume[s] and rel[ies] upon a functioning medical profession regulated under the States’ police powers.” *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

But neither FDA approval nor DEA’s five-part test examines whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used. Instead, FDA approval and DEA’s five-part test rely exclusively on certain scientific evidence and the views of some experts and FDA. Simp-

ly put, ignoring widespread clinical experience with a drug that is sanctioned by state medical licensing regulators when evaluating whether a drug has a CAMU is at odds with the plain meaning of section 812(b).⁵

Limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA's five-part test also conflicts with the text of section 812(b) by erroneously equating identification of an "accepted" medical use under the CSA with the "approval," or potential approvability, of the drug under the FDCA. Under the CSA, a substance can only be placed on Schedule I if it lacks *both* a "currently accepted medical use in treatment in the United States" *and* an "accepted safety for use . . . under medical supervision." 21 U.S.C. § 812(b)(1)(B), (C). By contrast, "the FDCA does not even mention the term 'medical use,'" *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987), and under the FDCA approval can be denied *either* because the drug is unsafe *or* because it is ineffective, *see* 21 U.S.C. § 355(d)(2), (5). FDA may also deny approval for several other reasons that have nothing to do with medical use, including that the application did not contain the necessary patent information, *see id.* § 355(d)(6), or that the methods used to manufacture, process, and pack the drug "are inadequate to preserve its identity, strength, quality, and purity," *id.* § 355(d)(3).

Moreover, other CSA provisions confirm that a drug having a CAMU is distinct from it being approved (or approvable) by FDA. Among other things, the CSA elsewhere repeatedly refers to, and in some places explicitly relies on, the FDCA. As an example, 21 U.S.C. § 829 prohibits the dispensing of "prescription drug[s] as determined under the [FDCA]" that are controlled under Schedules II through IV without a prescription from a practitioner, subject to certain exceptions. *See also, e.g., id.* §§ 811(g)(1), 825(e). Congress's decision to explicitly invoke the FDCA's standards with respect to some parts of the CSA, but not with respect to whether a drug has a CAMU, strongly suggests that it did not mean to equate CAMU with the standards necessary for FDA approval.

⁵ The First Circuit's decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), is not to the contrary. *Grinspoon* rejected the argument that Congress meant to privilege the views of "certain members of the medical community" in determining if a drug has a CAMU. *Id.* at 892. The court did not consider, however, the broader understanding of the relevant inquiry that we offer here—i.e., whether the medical community as a whole, including practitioners and regulators (among others), has "accepted" that a drug has a "medical use in treatment." 21 U.S.C. § 812(b)(1)(B).

Amendments to the CSA reinforce this conclusion. Congress added the “emergency scheduling” provision to the CSA in 1984. Pub. L. No. 98-473, § 508, 98 Stat. 1837, 2071–72 (1984) (codified as amended at 21 U.S.C. § 811(h)). That provision allows the Attorney General to place certain substances in Schedule I on a temporary basis without following the normal scheduling criteria if “necessary to avoid an imminent hazard to the public safety.” 21 U.S.C. § 811(h). But this authority does not apply where an “exemption or approval is in effect for the [drug] under section 505” of the FDCA—i.e., where FDA allows the drug to be marketed in interstate commerce. *See id.*; *see also* Controlled Substances Analogue Enforcement Act of 1986, Pub. L. No. 99-570, tit. I, subtit. E, 100 Stat. 3207, 3207-13 to -14 (codified as amended at 21 U.S.C. § 801(32)) (exempting drugs that have been approved by FDA from the definition of controlled substance analogue). As the First Circuit has observed, these provisions demonstrate that “absolute reliance on the absence of FDA approval” outside of these limited contexts “would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA.” *Grinspoon*, 828 F.2d at 890.

We recognize that our conclusion that DEA cannot rely exclusively on FDA approval or its five-part test in determining whether a drug has a CAMU is in some tension with the D.C. Circuit’s decisions in *ACT I* and *ACT II*. The record in those cases, however, was materially different from the one contemplated by HHS’s two-part inquiry: the petitioners in *ACT I* and *ACT II* had shown that, at most, a “number of physicians believe[d] that marijuana is medically useful”—evidence that the court twice said was “anecdotal.” *ACT I*, 930 F.2d at 939; *see also id.* (describing petitioner’s evidence as “largely anecdotal”). Indeed, although the court noted that it “ha[d] no grounds” on the record before it “to dispute [DEA’s] premise that without much more complete scientific data American physicians will not ‘accept’ marijuana,” it further observed that DEA’s conclusion would be “more vulnerable” if “virtually all doctors in the United States were vociferous in their espousal of marijuana for medical treatment—notwithstanding scientific uncertainties.” *Id.*; *see also ACT II*, 15 F.3d at 1134–35 (holding that DEA’s interpretation of “currently accepted medical use” was reasonable on law of the case grounds).

In other words, neither *ACT I* nor *ACT II* assessed DEA’s approach in the circumstance envisioned by HHS’s two-part inquiry—where there is

“widespread current experience with medical use of” a Schedule I drug in the United States by licensed health care practitioners “operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part I Analysis Memo at 1. To the contrary, the D.C. Circuit suggested that such circumstances might never occur, as one of its reasons for rejecting DEA’s original eight-part test was that it “appear[ed] impossible” for a Schedule I drug to meet the requirement that there be “[r]ecognition and use of the [drug] by a substantial segment of the medical practitioners in the United States.” *ACT I*, 930 F.2d at 938, 940. Yet with respect to at least one drug—marijuana—subsequent events have shown that a drug can be in Schedule I but still be recommended for medical use by a large number of medical practitioners in the United States. And for the reasons we have explained, when these circumstances exist, the plain text of section 812 mandates that they be taken into account when determining whether a drug has a CAMU.

B.

Having explained why DEA’s construction of the phrase “currently accepted medical use in treatment in the United States” is impermissibly narrow, we turn to why HHS’s two-part inquiry is sufficient to determine whether a drug has a CAMU.

1.

Part II.A explained that, to determine if a drug has a CAMU, section 812(b) requires an analysis of whether, at the present time, the medical community widely understands that a drug has a “use in treatment in the United States.” Although there is no single right answer as to *how* specifically DEA should make this determination, the text of the CSA establishes certain basic parameters to guide the inquiry.

As an initial matter, the definitions discussed above indicate that “accepted” means that something is “*widely* used or found” or “*generally* approved.” *Accepted*, Webster’s Third New International Dictionary 11 (emphasis added). It therefore follows from the word’s plain meaning that “anecdotal evidence” that a “number of physicians believe that [a drug] is medically useful” is not enough to show that the medical community has

accepted that a drug has a use in treatment in the United States. *ACT I*, 930 F.2d at 939. At the same time, however, “accepted” does not require universal consensus. Rather, it is sufficient if there is a widespread understanding in the medical community that a drug has a use in treatment.

Relatedly, nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition. So long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU. That reflects a basic reality about the medical profession: that “in medicine there is often a range of reasonable treatments[.]” *Young v. United States*, 942 F.3d 349, 352 (7th Cir. 2019).

Moreover, the medical community is not a monolith: It contains individuals and entities with a range of expertise and experiences, including licensed health care practitioners who specialize in certain areas of medicine, generalists with broader expertise, researchers, and regulators. In assessing the views of the medical community, section 812(b)(1)(B)’s emphasis on a “medical use in treatment” indicates that the views of all these constituencies are not equally important in every case. Instead, to determine whether the medical community understands using a particular drug to be within the range of reasonable treatment options, it is the views and practices of the health care practitioners who actually treat a given condition, as well as the regulators charged with enforcing applicable norms of practice, that are often especially relevant.

Finally, we believe a CAMU test must include consideration of the scientific evidence that supports the relevant medical use. This follows from section 811(c)’s requirement that the Attorney General “shall consider” eight factors in making the CAMU determination and other findings under section 812(b), some number of which inherently require consideration of scientific evidence. Although it is unclear exactly how the eight factors listed in section 811(c) correlate to the findings required by section 812(b), it is plain that at least two of those factors—the “scientific evidence of [the drug’s] pharmacological effect, if known” and the “state of current scientific knowledge regarding the drug,” 21 U.S.C. § 811(c)(2), (3)—bear on whether a drug has a currently accepted medical use, and that those factors necessarily require evaluation of scientific evidence. In addition, the requirement to consider “[w]hat, if any, risk there is to the

public health” and the drug’s “psychic or physiological dependence liability,” *id.* § 811(c)(6), (7), further suggests that an assessment of the available science is an integral part of a CAMU determination. Reviewing the available scientific evidence as part of the CAMU analysis is also consistent with the common-sense intuition that there is an inherent connection between whether the medical community has “accepted” a drug for “use in treatment,” *id.* § 812(b)(1)(B), and the scientific evidence supporting that conclusion. We generally would not expect the medical community to understand that it is reasonable to use a drug to treat a condition unless (as HHS suggests) there is at least some scientific evidence in support of that conclusion—evidence demonstrating, for example, that the drug was effective in treating the condition or does not create unacceptably high safety risks. HHS Part 2 Analysis Memo at 4–5.

2.

We conclude that HHS’s two-part inquiry falls within the basic parameters the CSA provides for establishing that a drug has a CAMU.

Part 1 of HHS’s test requires an assessment of whether health care practitioners are recommending that patients use a drug to treat a medical condition and whether they are doing so in accordance with guidelines issued by entities that regulate the practice of medicine. This approach is consistent with our view that determining whether a drug has a CAMU requires assessing whether there is a widespread understanding in the medical community that using the drug to treat a condition falls within the range of reasonable treatment options. In particular, the actual recommendations of practitioners made under applicable regulatory guidelines constitute strong evidence of whether the medical community understands a drug to be a reasonable treatment option.

The three non-dispositive factors HHS includes in its Part 1 analysis further demonstrate why its test is sufficient. Two of HHS’s factors look, respectively, at whether a “substantial number of licensed health care practitioners” have gained clinical experience with a drug under a state-authorized program and whether a “substantial number” of entities that regulate the practice of medicine have authorized the use of a drug for medical purposes. *See* HHS Part 1 Analysis Memo at 3. In our view, these inquiries provide good evidence of whether there is widespread agreement within the medical community that using the drug would be a reasonable

treatment option. Similarly, it is more likely that the medical community would widely understand that a drug represents a reasonable treatment option if HHS's third factor is present—i.e., that practitioners' clinical experience with the drug is of a "sufficient extent and duration" to help evaluate whether there are "potential clinical uses," "longer-term toxicities," and "potential harms." *Id.* at 5.

Moreover, Part 2 of HHS's test adequately takes the available scientific evidence into account by asking whether there is some credible scientific support for a least one of the medical uses for which the Part 1 test is met and then providing guidance as to what counts as "credible" scientific support. *See* HHS Part 2 Analysis Memo at 4 (identifying "favorable clinical studies" published in peer-reviewed journals as cutting in favor of the conclusion that the drug has a CAMU); *id.* (identifying data or information that "indicate[s] that medical use of the [drug] is associated with unacceptably high safety risks for the likely patient population" because of "toxicity concerns" as cutting against the conclusion that the drug has a CAMU). Neither section 811(c) nor section 812(b) requires a particular threshold of scientific support to conclude that a drug has a CAMU, and we believe that Part 2's requirement of some credible scientific support is sufficient in a context where health care practitioners have extensive experience with a drug and medical regulators have sanctioned the drug's use. Such clinical experience and regulatory sanction provide alternative sources of information about a drug, thereby making it reasonable not to require the high level of scientific support that might be demanded before a new and untried drug is determined to have a CAMU.

DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions. Specifically, DEA suggests that HHS's emphasis on states is "misplaced" because, in DEA's view, the processes states follow for enacting legislation "are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA." DEA Response at 11. But there is nothing in the text of the CSA that would warrant categorically discounting state practice in this fashion, particularly since doing so would be inconsistent with both the role of states as the central regulators of medical practice, *see Oregon*, 546 U.S. at 270, 274–75, and the fact that they are afforded "great leeway" in adopting measures to "protect public health and safety," *Mackey v. Montrym*, 443 U.S. 1, 17 (1979). Indeed, Congress has already

recognized the importance of states' views on whether marijuana in particular may be used to treat medical conditions by annually adopting an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *See supra* Part I.C.

In addition, states do often look to scientific and medical judgment in regulating medical marijuana. States typically only allow medical practitioners to recommend medical marijuana to treat specific conditions. *See, e.g.*, Ohio Rev. Code § 3796.01(A)(6)(a)–(v); N.Y. Cannabis Law § 3(18). In some states, practitioners may only recommend the use of medical marijuana after determining that the patient suffers from one of those conditions and that the “potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use.” *E.g.*, Conn. Gen. Stat. § 21a-408c(a); *see also* Fla. Stat. § 381.986(4). Several states have also established processes through which experts can recommend additions to, or removals from, the list of conditions that marijuana may be used to treat, *see, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c)(1), (d); Or. Admin. Rule 333-008-0090(3)(e), (4)(a)—indeed, HHS has informed us that 17 jurisdictions have added conditions that may be treated with marijuana using such processes, *see* HHS Part 1 Analysis Memo at 4. In short, it is simply not the case that state practice concerning medical marijuana is completely divorced from scientific and medical assessment.

III.

As discussed above, the CSA authorizes the Attorney General to place drugs in particular schedules if, after a formal rulemaking, the Attorney General makes certain findings. A particularly important finding is whether a drug has a CAMU, as the Attorney General may only keep or place a drug in Schedule I if it lacks a CAMU. Before initiating a rulemaking proceeding to schedule or reschedule a drug, however, the Attorney General is required to request recommendations from the Secretary that must include whether the drug has a CAMU. *See* 21 U.S.C. § 811(b). The CSA further makes these recommendations binding “as to” certain “scientific and medical matters.” *Id.*

Since HHS has recommended that marijuana has a CAMU, you have asked about the extent to which the “scientific and medical matters” that

are binding on the Attorney General, and thus DEA, include HHS's CAMU recommendation or any scientific and medical determinations underlying that recommendation. For the reasons that follow, we conclude, first, that HHS's overall CAMU recommendation is not binding on DEA. Second, we conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

A.

We first explain why HHS's overall CAMU recommendation does not bind DEA, starting with the two CSA provisions that govern the CAMU determination. Section 811(a) authorizes the Attorney General to schedule or reschedule a drug if the Attorney General makes certain findings "on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the APA]." Section 812(b) then lays out the relevant findings the Attorney General must make to schedule a drug, including whether the drug has a CAMU.

Taken together, these two provisions commit exclusively to the Attorney General the ultimate responsibility for making the findings required to schedule a drug, including a CAMU finding, and neither mentions the Secretary at all. Instead, the role of the Secretary is addressed in a separate provision of the CSA, section 811(b), which reads as follows:

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The

recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

This provision makes clear that the Secretary plays a crucial role in the scheduling process. It expressly directs the Attorney General to obtain a scheduling recommendation from the Secretary before initiating the scheduling process and to treat as binding certain “scientific or medical matters.” *Id.*⁶ But section 811(b) does not so much as mention the Secretary’s

⁶ In two recent rulemakings, DEA has stated that HHS’s scientific and medical recommendations only bind DEA with respect to factors (1), (4), and (5) of section 811(c). See 86 Fed. Reg. 29,506, 29,507–08 (June 2, 2021); 86 Fed. Reg. 27,803, 27,805 (May 24, 2021). This view appears to be based on a contrast in section 811(b)’s text: it directs the Secretary to “consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of [section 811(c)],” and “any scientific or medical considerations involved in paragraphs (1), (4), and (5) of [section 811(c)],” with the Secretary’s recommendations being “binding . . . as to such scientific and medical matters.” But section 811(b) highlights the “scientific and medical considerations” in factors (1), (4), and (5) not because HHS should consider the science and medicine underlying only those factors, but rather because those factors all relate to a drug’s abuse potential, the analysis of which Congress understood as resting primarily on law enforcement considerations. See H.R. Rep. No. 91-1444, at 33–36; House Hearing at 718. By comparison, there is no need to direct HHS to consider the “scientific or medical considerations” involved with factors (2), (3), (6), (7), and (8) since those factors involve inquiries that are predominantly, if not entirely, scientific and medical in nature. We thus think it plain that HHS’s recommendations with respect to “scientific and medical matters” are binding for all eight factors listed in section 811(c). See H.R. Rep. 91-1444, at 33; see also *id.* at 22–23 (“[A]ll scientific and

CAMU recommendation. Instead, section 811(b) expressly identifies a different circumstance in which the Secretary’s recommendation concerning an ultimate scheduling determination is dispositive: when the Secretary recommends against controlling a drug. This fact—that section 811(b) identifies a separate scheduling recommendation as binding—makes its silence on the Secretary’s CAMU recommendation all the more conspicuous.

Moreover, we do not believe the Secretary’s authority to bind the Attorney General with respect to “scientific and medical matters” encompasses a CAMU determination, because such a determination involves judgments that are neither wholly scientific nor wholly medical. For example, as the discussion in Part II indicates, assessing whether a drug has a CAMU may involve, in part, determining whether the extent of medical use present is sufficient to qualify as “accepted” within the medical community. 21 U.S.C. § 812(b)(1)(B). This inquiry is more akin to the application of a legal standard to a set of facts than a judgment necessarily requiring medical or scientific expertise, as it could turn (at least in part) on reasoning or facts that are neither scientific nor medical in nature, such as determining how many states have authorized use of a drug in treating a medical condition. *Cf., e.g., United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (conclusions that are the “product of reasoning processes familiar to the average person in everyday life” do not require specialized expertise); *accord United States v. Vega*, 813 F.3d 386, 394–95 (1st Cir. 2016) (conclusions based on “logic and pattern recognition” do not require specialized expertise). Because a CAMU determination can include elements that fall outside the substantive scope of HHS’s authority to bind DEA, HHS’s overall determination that a substance has (or lacks) a CAMU cannot be binding.

B.

We next explain why the scientific and medical determinations underlying HHS’s overall CAMU recommendations bind DEA, although only until the initiation of formal rulemaking, and why DEA is nonetheless obligated to accord the findings significant deference thereafter.

medical determinations [will be] made by the Secretary of Health, Education, and Welfare[.]” (emphasis added)).

As a threshold matter, the text and legislative history of section 811(b) demonstrate that the “scientific and medical matters” binding on the Attorney General include the scientific and medical determinations that underlie the Secretary’s CAMU recommendation. *See* H.R. Rep. No. 91-1444, at 33; HHS Response at 10; DEA Response at 16. For example, whether some credible scientific support exists for a particular widespread clinical use, *see supra* Part I.C, is undoubtedly relevant to a CAMU finding—and undoubtedly a “scientific and medical matter.”

The more difficult question, however, is whether HHS’s scientific and medical determinations remain binding throughout the scheduling process—a question on which DEA and HHS hold sharply different views. DEA argues that it “is only bound by HHS’s evaluation as to scientific and medical matters . . . at the beginning of the [scheduling] process,” but “[o]nce rulemaking has begun, DEA can—and must—consider material submitted during the administrative process in reaching a final scheduling determination.” DEA Response at 13; *see also* 76 Fed. Reg. 77,330, 77,334–36 (Dec. 12, 2011) (adopting this position). HHS takes the opposite view, arguing that its scientific and medical recommendations bind DEA throughout the scheduling process, including the formal rulemaking. *See* HHS Response at 10–11.

The CSA is unquestionably hard to parse on this issue. It does not expressly address for what portion of the administrative proceedings HHS’s determinations are binding, nor does it specify how, if at all, such determinations must be considered during the formal rulemaking proceedings. Moreover, what clues the statute does offer point in two opposing directions: On the one hand, the statute requires the Attorney General alone to make the ultimate findings required for scheduling after an on-the-record formal rulemaking, which implies that the Attorney General must consider contrary scientific or medical evidence submitted during that process. *See* 21 U.S.C. § 811(a). On the other hand, the statute makes the Secretary’s scientific and medical determinations “binding” on the Attorney General without expressly limiting the binding nature of those determinations to any particular stage of the scheduling process. *See id.* § 811(b).

Although a close question, we think Congress’s decision to make scheduling decisions subject to a formal rulemaking process ultimately provides the answer. Fundamentally, the proposition that HHS’s determinations bind DEA for the entirety of the scheduling process cannot be

squared with the nature of the formal rulemaking that section 811(a) requires. Nothing in the CSA limits outside participants to submitting only nonscientific and nonmedical evidence at a rulemaking hearing. Given the possibility that parties may submit contrary scientific or medical evidence, construing section 811(b) to preclude DEA from considering such evidence would be inconsistent with the APA's requirement that rules issued via formal rulemaking be based "on consideration of the whole record . . . and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement . . . [to] consider the whole record."). In short, DEA would not be making a decision based on the "whole record" and "in accordance with the reliable, probative, and substantial evidence," 5 U.S.C. § 556(d), if HHS's determinations barred DEA from considering contrary scientific or medical evidence. Two courts of appeals have suggested in dicta that they view the issue similarly. *See Grinspoon*, 828 F.2d at 890; *Reckitt & Colman, Ltd. v. Administrator, DEA*, 788 F.2d 22, 27 n.8 (D.C. Cir. 1986).

The fact that HHS's recommendations as to certain "scientific and medical matters" do not bind DEA for the entire scheduling process does not mean, however, that they are without effect. Rather, in order to give force to the statutory command that HHS's recommendations "bind[]" DEA, we believe HHS's scientific and medical determinations must be binding until the issuance of a notice of proposed rulemaking ("NPRM"). Up to this point, the formal rulemaking procedures required by section 811(a) are not yet in effect, *see* 21 C.F.R. §§ 1308.43(f), 1316.42(g), meaning there is no conflict between the statutory commands to consider contrary evidence in the record and accord binding effect to HHS's recommendations.

In addition, DEA may not simply cast aside HHS's scientific and medical recommendations once it initiates formal rulemaking proceedings by issuing an NPRM. The categorical use of the word "binding" in section 811(b) suggests that Congress intended HHS's scientific and medical views to at least be a very significant input in the scheduling process. And there would seem to be little reason to make the HHS's views binding at any stage in the process if DEA eventually could discard HHS's determi-

nations and review scientific and medical matters *de novo*. Cf. *Reno v. Am.-Arab Anti-Discrimination Comm.*, 525 U.S. 471, 487 (1999) (statutes should be read in a manner that “makes sense of the statutory scheme as a whole”).

The legislative history of the CSA supports the view that HHS’s scientific and medical determinations should remain significant throughout the rulemaking process. The House report on the CSA states that Congress intended “all scientific and medical determinations” to be “made by the Secretary,” rather than the Attorney General, and nothing in the legislative history suggests that the Attorney General would be free to make *de novo* scientific and medical judgments once the formal rulemaking is underway. H.R. Rep. No. 91-1444, at 22–23. Indeed, the House report emphasized that section 811 was “not intended to authorize the Attorney General to undertake or support medical and scientific research” for the purpose of scheduling, as that research “is within the competence of [HHS].” *Id.* at 33. And considering this same legislative history, the Supreme Court noted in *Gonzales* that the CSA places “medical judgments” made under the Act in the “hands of the Secretary.” 546 U.S. at 265.

We therefore conclude that, to give proper effect to HHS’s scientific and medical determinations, DEA must continue to accord significant deference to those determinations even once formal rulemaking has commenced and may not undertake a *de novo* assessment of HHS’s findings at any point in the rulemaking process.

IV.

The Single Convention requires parties to impose controls on the cultivation, manufacture, and distribution of various drugs, including “cannabis.”⁷ Among other things, parties to the Convention generally must

⁷ The Convention defines “cannabis” as “the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.” Single Convention art. 1(1)(b). We understand the marijuana in use in the United States to fall within this definition, although the definition of cannabis under the Single Convention is slightly less inclusive than the CSA’s definition of “marihuana,” which includes all parts of the *Cannabis sativa* L. plant with certain exceptions, including mature stalks and sterilized seeds that are incapable of germination. See 21 U.S.C. § 802(16).

require that manufacturers, distributors, importers, and exporters of cannabis secure a license, Single Convention arts. 29–31; impose quotas on the import and manufacture of cannabis, *id.* art. 21(1); generally prohibit the unauthorized possession of cannabis, *id.* art. 33; and adopt penal provisions making violations of the controls required by the Convention punishable offenses, *id.* art. 36.

Several provisions of the CSA—including sections 801(7), 811(d)(1), 812(b), 823(a), 953(a), and 958(a)—“reflect Congress’s intent to comply with the obligations imposed by the Single Convention.” *Control of Papaver bracteatum*, 1 Op. O.L.C. 93, 95 (1977). Of particular relevance here, section 811(d)(1) provides:

If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures described by subsections (a) and (b) of this section.

The Single Convention entered into force for the United States on June 24, 1967, and was thus “in effect on October 27, 1970.” *Id.* Both our Office and the D.C. Circuit have interpreted section 811(d)(1) to apply to any scheduling action by the Attorney General concerning a drug covered by the Single Convention, including actions to transfer a drug between schedules. Memorandum for John E. Ingersoll, Director, Bureau of Narcotics & Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Petition to Decontrol Marihuana; Interpretation of Section 201 of the Controlled Substances Act of 1970* at 9 (Aug. 21, 1972) (“Lawton Memo”); *NORML II*, 559 F.2d at 747.

Given this, your third question asks whether the CSA or the Single Convention requires marijuana to be placed in Schedule I or Schedule II. This question is one our Office has considered before: in 1972, we concluded that the Convention requires marijuana to be placed in Schedule I or II because placing marijuana in Schedules III, IV, or V would not enable the United States to satisfy its Convention obligations. *See* Lawton Memo at 12–13. In particular, we emphasized that the “quotas on manu-

facture and importation of a substance required by the Convention could not be maintained under existing statutory authority were marihuana listed in Schedules III, IV, or V.” *Id.*; see also *NORML II*, 559 F.2d at 750–51 (agreeing with the Lawton Memo that Schedule I or II was necessary to meet the United States’ Single Convention obligations). In reaching this conclusion, however, we did not address an issue that both HHS and the State Department now ask us to consider: whether under the CSA the United States can comply with its Single Convention obligations by placing marijuana in Schedule III while “adopting such additional regulations as are necessary for treaty compliance.” HHS Response at 13; State Response at 5–7; see also *NORML II*, 559 F.2d at 752–53 (recognizing the possibility of a similar regulatory approach but taking no position on its availability).

We think this question is a close one. For the reasons that follow, however, we believe that the Single Convention does not require DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule. And consistent with this conclusion, we believe DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA’s regulatory authorities.

A.

To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory “schedule” that specifically authorizes all the necessary restrictions. To the contrary, the Single Convention states that parties will implement the Convention using both “laws and *regulations*.” Single Convention art. 18(1)(b) (emphasis added); see also *id.* art. 4 (referring to the use of “legislative and *administrative measures*” to carry out the Single Convention (emphasis added)). The Single Convention thus appears to explicitly contemplate a scenario in which DEA decides to implement the United States’ obligations through a combination of scheduling and regulatory actions.

As a result, any limitation on satisfying the United States’ Single Convention obligations by supplementing a scheduling decision with regulatory action would have to come from domestic law. Nothing in the CSA, however, states that a drug must be placed into Schedule I or II, or any other particular schedule, to comply with the Single Convention. Nor does the CSA expressly foreclose DEA from satisfying the United States’ international obligations with a combination of scheduling and regulatory actions. Rather, section 811(d)(1) directs the Attorney General to “control[]” a drug “under the schedule [the Attorney General] *deems most appropriate*” (emphasis added)—language that signals a broad grant of discretion to the Attorney General (and thus DEA), *see Rex Chainbelt, Inc. v. Volpe*, 486 F.2d 757, 761 (7th Cir. 1973). To be sure, the very same language could be read to mean that DEA must select a schedule without resort to regulatory supplementation. *See* 21 U.S.C. § 802(5) (defining “control” as “to add a drug . . . to a *schedule*” (emphasis added)). But we are reluctant to adopt a restrictive reading of such broad discretionary language, particularly when doing so would preclude DEA from relying on regulatory supplementation to close even relatively minor gaps between a schedule and the United States’ international obligations. Indeed, consistent with this reading, DEA has previously placed a drug with the psychoactive chemicals found in cannabis into Schedule V and then imposed additional controls through regulation to comply with the United States’ international obligations. *See* 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018).⁸

The CSA’s varied, and potentially conflicting, purposes further show why it is appropriate to read section 811(d)(1)’s broad grant of authority in this way. Consider a hypothetical case in which the Single Convention imposes obligations that DEA determines would, absent regulatory action,

⁸ We have taken a similar interpretive approach to section 811(d)(1)’s language specifying that the Attorney General meet international obligations “without regard” to the findings and procedures otherwise required by sections 811(a) through (b) and 812(b). Rather than viewing this language as precluding the Attorney General from following ordinary scheduling practices when international obligations are involved, both our Office and the D.C. Circuit have understood it to allow the Attorney General to identify which schedules would satisfy the United States’ international obligations with respect to a particular drug, and then—if more than one schedule would do so—select which schedule to use through the section 811(a) through (b) and 812(b) procedures. Lawton Memo at 10; *accord NORML II*, 559 F.2d at 747.

require placement on Schedule I or Schedule II, but DEA has also determined that the same drug's abuse potential, medical usefulness, and health effects warrant placing the drug in Schedule III. *See* 21 U.S.C. §§ 801(1), (2), 812(b)(3). In such a circumstance, reading section 811(d)(1) to allow for consideration of regulatory action allows DEA to conclude that Schedule III is the "most appropriate" schedule by pairing that choice with regulatory actions that ensure compliance with the Single Convention. This enables DEA to comply with the United States' international obligations while furthering the CSA's other purposes, thus fulfilling both sets of objectives.

The broad regulatory authority provided by the CSA further suggests that DEA need not rely on scheduling decisions alone to comply with the Single Convention. The CSA authorizes the Attorney General (and thus DEA) both to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," *id.* § 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions," *id.* § 871(b). Courts recognize that broad, discretionary language such as this conveys "extensive" regulatory authority, *Volpe*, 486 F.2d at 761; *see also, e.g., Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1209 (D.C. Cir. 2020)—and, here, the language by its plain terms would seem to encompass regulatory actions that DEA may take to satisfy Single Convention obligations not met by a drug's schedule alone.

Likewise, the CSA provides the Attorney General with a number of more specific regulatory authorities that DEA may use to enable compliance with particular Single Convention obligations, such as the CSA's registration requirements. Subject to certain limited exceptions, section 822(a) requires "[e]very person who manufactures or distributes" or "dispenses" a drug to "obtain annually a registration issued by the Attorney General in accordance with rules and regulations promulgated by him," and section 822(b) further specifies that "[p]ersons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration." These provisions give DEA the authority to impose a number of controls on a particular drug through registration. Other CSA

provisions provide similar regulatory authority that could enable a drug on a schedule other than Schedule I or Schedule II to comply with the Single Convention. *See, e.g.*, 21 U.S.C. §§ 823(e), (f), 827(e), 952(b)(2), 953(e)(2), 958(c).

Finally, past practice also supports our conclusion. Specifically, in addition to the example recounted above of DEA imposing additional controls through regulation to comply with the United States' international obligations, *see* 83 Fed. Reg. at 48,952, we understand that DEA previously has relied on a combination of the Attorney General's registration power and general regulatory authority to promulgate extensive safety and security regulations that govern manufacturers and distributors of controlled substances. *See* 21 C.F.R. §§ 1301.71–.77. And our Office has previously read the Attorney General's authority to register manufacturers broadly to permit the imposition of certain controls that would enable compliance with the Single Convention. *See Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs*, 42 Op. O.L.C. ___, at *24 (June 6, 2018) (“*Licensing Marijuana Cultivation*”). These prior regulatory actions indicate that the broad and varied provisions discussed above provide authority that may be used to impose additional controls to satisfy the United States' international obligations.

We recognize that reading the CSA as allowing DEA to use regulatory authorities to close gaps in our compliance with international obligations could be viewed as in tension with certain aspects of the CSA's text and structure. As the Lawton Memo noted, several provisions of the CSA implementing controls required by the Single Convention draw a distinction between Schedules I and II, on the one hand, and Schedules III through V, on the other, in a manner that can be read to suggest that Congress understood the United States would comply with its Convention obligations by placing drugs into Schedules I or II. Lawton Memo at 12; *see, e.g.*, 21 U.S.C. §§ 823(a), (d), (e), 826(a), 842(b), 952(a), (b), 958(a), (c). Moreover, Congress designed the CSA to include five schedules, each with a distinct bundle of requirements and consequences, and allowing DEA to add or subtract controls would arguably have the practical effect of enabling DEA to create new schedules.

These arguments have some force, but they do not carry the day. Since the CSA's enactment, Congress has amended the Act in a manner that indicates the distinction between Schedules I and II and Schedules III

through V may not be as sharp as the argument above suggests. *See infra* Part IV.B (describing how amendments that added sections 952(b)(2), 953(e)(2), and 827(e) enable the United States to meet certain Single Convention obligations while placing nonnarcotic drugs in Schedule III). In any event, right alongside the provisions that could *impliedly* suggest Schedules I and II will be used to comply with the United States' Single Convention obligations are provisions that *expressly* grant the Attorney General (and thus DEA) both broad discretion to select the schedule "most appropriate" to satisfy the United States' international obligations, *see* 21 U.S.C. § 811(d)(1), and broad regulatory authority, *see, e.g., id.* §§ 821, 871(b). And given the plain meaning of the CSA's regulatory provisions, we do not believe that the CSA's five-schedule structure can be reasonably understood to preclude DEA from taking at least some regulatory actions to comply with the United States' international obligations. Indeed, it would be particularly strange to view DEA as so constrained in the context of treaty compliance, given section 811(d)(1)'s express grant of broad discretion to meet international obligations. We therefore believe that something more than such textual and structural inferences are needed to foreclose use of these broad and express statutory grants of regulatory authority to impose additional controls to meet the United States' international obligations.

Thus, while we take no position on the full extent to which DEA may use the CSA's broad regulatory authority to impose additional controls to meet international obligations, we do not read the CSA as precluding DEA from ever satisfying the United States' Single Convention obligations by supplementing scheduling decisions with regulatory action. Rather, we believe that the CSA provides DEA with the discretion to decide, at least in some circumstances, that such a scheduling and regulatory approach is the most appropriate way to strike a balance between the CSA's varied—and potentially conflicting—purposes of curtailing the improper use of drugs with abuse potential, complying with the United States' international obligations, and ensuring that medically useful drugs remain available for legitimate purposes. *See* 21 U.S.C. § 801(1), (2), (7).

B.

We next consider the specific question of whether DEA may comply with the United States' obligations under the Single Convention by supplementing a decision to place marijuana in Schedule III with regulatory action.

As a threshold matter, we understand that, if marijuana were placed on Schedule III, the gap that DEA would need to fill would be modest. To be sure, the Lawton Memo and the D.C. Circuit expressed concern that placing marijuana into Schedule III would create compliance concerns with respect to certain Single Convention requirements. In its submission to us, however, the State Department observed that, even if marijuana were listed in Schedule III, most of the United States' Single Convention obligations would continue to be met. *See* State Response at 4–7. The State Department's view reflects amendments to the CSA that postdate the Lawton Memo (from 1972) and the D.C. Circuit's consideration of the issue (in 1977) and that specifically authorize certain controls required by the Single Convention to be placed on drugs outside Schedules I and II. Given these amendments, many of the gaps previously identified in Single Convention compliance would no longer exist if marijuana were placed in Schedule III.

In particular, the Lawton Memo and D.C. Circuit both pointed to the manufacturing and import quotas required by Article 21 of the Single Convention as potential gaps, *see* Lawton Memo at 12–13, while the D.C. Circuit also identified the estimates and statistical reports required by Articles 19 and 20 and the import and export authorizations required by Article 31(4), *see NORML II*, 559 F.2d at 751 n.71. In 1978, however, Congress enacted 21 U.S.C. § 827(e), which specifically authorizes the Attorney General, among other things, to prescribe measures necessary to comply with the reporting requirements of Articles 19 and 20 of the Single Convention for drugs in any schedule, not just those in Schedules I and II. *See* Psychotropic Substances Act of 1978, Pub. L. No. 95-633, § 104, 92 Stat. 3768, 3772. In addition, in 1984 Congress amended the CSA provisions that implement the import and export permit requirements to specifically authorize the use of permits for a nonnarcotic Schedule III drug. *See* 21 U.S.C. §§ 952(b)(2), 953(e) (enacted by the Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473,

§§ 521–522, 98 Stat. 1837, 2075–76). If marijuana, a nonnarcotic drug, were placed in Schedule III, we believe these statutory provisions would ensure compliance with both the import quota obligation of Article 21 and the import and export authorization requirements of Article 31(4).

These subsequent enactments address most of the concerns the Lawton Memo and D.C. Circuit identified, with the exception of the manufacturing quota requirements of Article 21 of the Convention. But we believe this remaining gap is addressable using the CSA’s regulatory authorities. Several different authorities appear potentially applicable. A regulation imposing a manufacturing quota on a drug would fall easily within the broad language of section 821, as it would be “relat[ed] to the . . . control of the manufacture” of a drug. 21 U.S.C. § 821. DEA likewise could deem a regulation imposing a manufacturing quota as “necessary and appropriate for the efficient execution of” the CSA function of controlling drugs to meet the United States’ international obligations. *Id.* § 871(b); *see id.* § 811(d)(1). By their plain terms, the CSA’s registration authorities would also give DEA the authority to impose a manufacturing quota on a particular drug through regulation: no person can manufacture a drug (including marijuana) without a registration issued by DEA, *see id.* § 822(a), and in that registration DEA can limit the “extent” to which any person is “authorized to . . . manufacture” marijuana under their registration, *id.* § 822(b). Section 823(e) provides yet another potential source of authority for imposing a manufacturing quota on a Schedule III drug, as DEA could conclude under section 823(e) that registrations to manufacture marijuana would be “inconsistent with the public interest” unless a quota consistent with Article 21 of the Single Convention was implemented to maintain “effective controls against diversion.” *Id.* § 823(e); *see also Oregon*, 546 U.S. at 260 (identifying similar language in section 823(a) as providing regulatory authority).⁹

⁹ We note that section 823(a) provides that the Attorney General shall register manufacturers of Schedule I and Schedule II drugs upon determining that “such registration is consistent with the public interest and with *United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.*” (Emphasis added.) In *Licensing Marijuana Cultivation*, we emphasized section 823(a)’s invocation of international obligations in concluding that DEA could promulgate regulatory controls necessary to meet certain of the United States’ obligations under the Single Convention. *See* 42 Op. O.L.C. ___, at *24. Although section 823(e) does not include a similar requirement to

In concluding that the CSA provides numerous sources of authority that could be used to impose a manufacturing quota, we recognize that section 826 expressly requires manufacturing quotas for drugs in Schedules I and II.¹⁰ But that requirement should not be read as implicitly foreclosing the imposition of such quotas for drugs in Schedules III through V. As the D.C. Circuit has recognized, “a congressional mandate in one section and silence in another often suggests not a prohibition but simply a decision . . . to leave the question to agency discretion.” *Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam) (quotation marks omitted).

We therefore conclude that both the Single Convention and the CSA permit DEA to place marijuana in Schedule III while imposing additional controls, pursuant to the CSA’s regulatory authorities, to close a modest gap between the requirements of the Single Convention and the requirements that follow from placement on Schedule III.

V.

For the reasons set forth above, we conclude, first, that DEA’s current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by

consider international obligations, it does require the Attorney General to consider whether registration is “inconsistent with the public interest,” 21 U.S.C. § 823(e), and complying with the United States’ international obligations is plainly in the public interest. Against this backdrop, we do not read Congress’s silence with respect to international obligations in section 823(e) as precluding DEA from relying on that section to comply with international obligations. *See Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam).

¹⁰ Although the CSA refers to quotas on the “production” of drugs and the Single Convention to quotas on the “manufacture” of drugs, we understand the scope of these terms to largely overlap. The CSA defines “production” to include the “manufacture, planting, cultivation, growing, or harvesting of a controlled substance,” 21 U.S.C. § 802(22), and, in turn, defines “manufacture” to include the “production, preparation, propagation, compounding, or processing of a drug,” *id.* § 802(15). The Single Convention defines “manufacture” to mean “all processes . . . by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs,” Single Convention art. 1(1)(n), but excludes “the separation of . . . cannabis and cannabis resin from the plants from which they are obtained,” *id.* art. 1(1)(t).

FDA and would not satisfy DEA's five-part test. Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA and that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rule-making proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process. Finally, we conclude that neither the Single Convention nor the CSA requires marijuana to be placed into Schedule I or II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific restrictions that follow from a drug's placement on a particular schedule. As a result, DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA's regulatory authorities.

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Office of Legal Counsel

Exhibit B

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of

Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

Docket No. 22-15

ORDER GRANTING IN PART GOVERNMENT’S MOTION TO DISMISS IN PART

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM), with the docket number DEA-623, titled “Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I.” 87 Fed. Reg. 2376 (2022). The NPRM proposes to place the five tryptamine hallucinogens (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT) in schedule I of the Controlled Substances Act (CSA). *Id.* On January 31, 2022, Panacea Plant Sciences (Panacea) filed a Request for Hearing (RFH). On February 14, 2022, Jason Wallach and Hamilton Morris, Kykeon Biotechnologies Inc. (Mindstate) and Tactogen Inc. (Tactogen), and Amy Rising filed RFHs.

On April 18, 2022, the Government filed its Motion to Dismiss in Part (Government’s Motion) alleging that not all parties requesting a hearing have standing and asking this tribunal to dismiss “any party that cannot establish interested person status for at least one of the substances[.]”¹ Gov’t Mot. at 1. Additionally, the Government requests that this tribunal “limit

¹ The Government concedes that Jason Wallach and Hamilton Morris, who are proceeding jointly, established standing in their RFH with respect to DiPT. Gov’t Mot. at 9. In the April 26, 2022 status conference, counsel for Dr. Wallach and Mr. Morris indicated that they only intended to request a hearing with respect to the proposed scheduling of DiPT and do not wish to challenge the proposed scheduling of the other four tryptamines. Accordingly, Dr. Wallach and Mr. Morris’ standing to challenge the proposed scheduling of DiPT is not challenged herein.

the hearing on this proposed rulemaking to those substances for which an interested person has requested a hearing.” *Id.* at 1-2.

ADMINISTRATIVE STANDING

“The starting point in determining administrative standing should be the language of the statutes and regulations that provide for an administrative hearing, appeal or intervention.” *Koniag, Inc., Uyak v. Andrus*, 580 F.2d 601, 614 (D.C. Cir. 1978) (Bazelon, J., concurring); *see Koniag*, 580 F.2d at 606. The standing analysis is thus an individualized one, within the context of the regulations and the statutory scheme as a whole. *Nichols v. Bd. of Trs.*, 835 F.2d 881, 896 n.108 (D.C. Cir. 1987).

This is a scheduling proceeding under § 811 of the CSA. The regulations governing scheduling proceedings provide that an “interested person” may request a hearing on the proposed scheduling of a substance. *See* 21 C.F.R. § 1308.44. The regulations define “interested person” as “any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant” to 21 U.S.C. § 811. *Id.* § 1300.01. A person requesting a hearing must state “with particularity” his interest in the proceeding. *Id.* § 1316.47(a).

The Agency has not interpreted either “interested person” or “any person adversely affected or aggrieved,” although there are two Agency rulemaking proceedings in which the Agency found a party requesting a hearing did not meet the definition of “interested person.” *See Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013) (denying a request for hearing because a concern that the substance had a large potential for abuse was insufficient to show that the party requesting a hearing was an “interested person”); *Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009) (denying a request for hearing because the party’s statement that “lack of information and inappropriate comparisons to other drugs precluded the scheduling” did not sufficiently establish standing as an “interested person”).

In the absence of an official Agency interpretation, this tribunal looks to general principles on standing. Standing to sue in federal court stems from the Article III case or controversy requirement and thus requires injury-in-fact. *See, e.g., Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338-39 (2016). Moreover, federal courts have put on a “judicial gloss” of prudential standing called the “zone of interests” test limiting who may challenge an agency action. *See Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994). But standing before an administrative agency is

more permissive than before an Article III court. *See Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002) (“Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action.”); *Envirocare, Inc. v. NRC*, 194 F.3d 72, 74 (D.C. Cir. 1999) (“Agencies, of course, are not constrained by Article III of the Constitution; nor are they governed by judicially-created standing doctrines restricting access to the federal courts. The criteria for establishing ‘administrative standing’ therefore may permissibly be less demanding than the criteria for ‘judicial standing.’”); *Nichols*, 835 F.2d at 896 n.108 (“We emphasize that parties may validly participate in agency proceedings even absent standing to obtain judicial review.”); *Koniag*, 580 F.2d at 606 (a party need not be “excluded from participation before the agency if it does not have a sufficient interest to meet Article III requirements for judicial review.”).

Applying the “‘interested person’ concept to parties not entitled to judicial review resists precise legislative or judicial delineation, and requires close scrutiny, in the context of the statutory and regulatory schemes governing the proceedings in which intervention is sought, of the private interest asserted.” *Nichols*, 835 F.2d at 896 n.108 (internal citations omitted). Thus, standing before an agency is not synonymous with standing before a federal court and requires a close examination of the applicable regulations. *Id.*; *see also Koniag*, 580 F.2d at 614. More precisely, the question here is what “adversely affected or aggrieved” requires within the context of the CSA and the limited Agency caselaw for standing in these proceedings.

The Agency has taken the position, in the context of mootness, that it is not bound by Article III. *See, e.g., The Pharmacy Place*, 86 Fed. Reg. 21008, 21008 (2021); *Jeffrey D. Olsen, M.D.*, 84 Fed. Reg. 68474, 68476 (2019).

The subject matter of agencies’ jurisdiction naturally is not confined to cases or controversies inasmuch as agencies are creatures of [A]rticle I. Though agencies must act without arbitrariness, . . . still agencies are generally free to act in advisory or legislative capacities...[which] is obvious in the case of rulemaking[.]

Olsen, 84 Fed. Reg. at 68478 (quoting *Tennessee Gas Pipeline v. Fed. Power Comm’n*, 606 F.2d 1373, 1379 (D.C. Cir. 1979)). While not directly on point, the Agency’s position is instructive given that courts have routinely stated that (with some caveats): “the doctrine of mootness can be described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189-90 (2000)

(internal quotations omitted) (noting exceptions to this rule). Given that the Administrator has rejected the application of Article III in the context of mootness in Agency proceedings, the logical extrapolation of those decisions is that § 1300.01 does not incorporate the requirements of Article III standing.

The Government, however, argues that “adversely affected or aggrieved” applies no differently here than how it has historically been interpreted in federal courts. Gov’t Mot. at 4-5. “The phrase ‘person adversely affected or aggrieved’ is a term of art used in many statutes to designate those who have *standing to challenge* or appeal an agency decision, *within the agency* or before the courts.” *Id.* at 4 n.1 (emphasis in original) (quoting *Dir., Off. of Workers’ Comp. Programs, Dept. of Lab. v. Newport News Shipbuilding and Dry Dock Co. (Newport News)*, 514 U.S. 122, 126 (1995)). The phrase appears in the judicial review provision of the Administrative Procedure Act (APA) and similarly appears in the CSA’s judicial review provision. *See* 5 U.S.C. § 702 (“A person...adversely affected or aggrieved by agency action within the meaning of the relevant statute[] is entitled to judicial review thereof.”); 21 U.S.C. § 877 (“any person aggrieved by a final decision of the Attorney General may obtain review of the decision”). Courts have interpreted the APA’s judicial review provision as requiring a party to show that he is both “injured in fact by agency action and that the interest he seeks to vindicate is arguably within the ‘zone of interests to be protected or regulated by the statute’ in question.” *Newport News*, 514 U.S. at 127 (quoting *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Additionally, courts interpreting the CSA’s judicial review provision have similarly found that it “merely requires that the litigant have Article III standing and prudential standing—i.e., arguably be within the ‘zone of interests.’” *Bonds v. Tandy*, 457 F.3d 409, 413 (D.C. Cir. 2006); *see PDK Lab’ys Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004).

The Government’s interpretation of *Newport News*, however, is too broad. That decision—which involved federal judicial review—stands merely for the proposition that a party challenging an agency decision *in federal court* lacks standing unless the party can establish it had injury-in-fact and fell within the statute’s zone of interests from the very beginning of the case, including before the Agency. *Newport News*, 514 U.S. at 126. But it does not support the proposition that a party must be excluded from *an agency proceeding* if it fails to make that showing. *See Gettman*, 290 F.3d at 434; *Koniag*, 580 F.2d at 606. Similarly unpersuasive are the other cases cited by the Government. While courts have interpreted “adversely affected or aggrieved” as requiring Article

III and prudential standing, those courts were examining statutory provisions establishing standing to seek judicial review before a federal court, not standing before an agency. *See Newport News*, 514 U.S. at 127; *Bonds*, 457 F.3d at 413; *PDK Lab 'ys*, 362 F.3d at 793. As discussed above, courts have repeatedly rejected the presumption that Article III applies to agency proceedings, as has this Agency, in the context of mootness. Moreover, the Government's argument runs counter to the established principle that administrative standing is more permissive than Article III standing. *See Gettman*, 290 F.3d at 434. Accordingly, the Government's argument is unpersuasive.²

The parties find common ground on applying the zone of interests test, which provides that a party requesting a hearing must have an interest in these proceedings and that interest must be "arguably within the zone of interests..." *PDK Lab 'ys*, 362 F.3d at 791 (quoting *Ass'n of Data Processing*, 397 U.S. at 153). The parties requesting a hearing have the burden of proving that they have standing to participate in these proceedings.³ The test is "not meant to be especially demanding[;]" however, where the party is not the subject of the agency action, the party's interests must not be "so marginally related to or inconsistent with the purposes implicit in the statute." *Clarke v. Secs. Indus. Ass'n.*, 479 U.S. 388, 399 (1987). A party falls "within the zone of interests if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998) (citing *First Nat'l Bank & Tr. Co. v. Nat'l Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993)). To be clear, "[j]udicially-devised prudential standing requirements, of which the 'zone of interests' test is one, are also inapplicable to an administrative agency...The doctrine of prudential standing, like that derived from the Constitution, rests on considerations 'about the proper—and properly limited—role of the courts in a democratic society.'" *Envirocare*, 194 F.3d at 75 (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). But, while prudential standing is not necessarily required for administrative standing, absent additional guidance from the Agency, the zone of interests standard provides an instructive framework to interpret the meaning of "adversely affected or aggrieved."

² Even if the regulations require injury-in-fact, that would not change the outcome of this case. *See infra* note 4.

³ While 21 C.F.R. § 1316.56 provides that the moving party has the burden of proof, the regulations require that the party requesting a hearing demonstrate their interest in these proceedings at the outset. *See* 21 C.F.R. § 1316.47(a).

For these proceedings, the CSA and, specifically, § 811 establish the zone of interests. The overall purpose of the CSA is “to protect the public from the deleterious effects of the illegitimate use and distribution of controlled substances.” *Bonds*, 457 F.3d at 415; *see Gonzales v. Oregon*, 546 U.S. 243, 250 (2005) (the CSA was enacted with “the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances”). To accomplish its purpose, “the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the [CSA’s] five schedules.” *Gonzales*, 546 U.S. at 250. Section 811 regulates how substances may be added, removed, or transferred between the five schedules. 21 U.S.C. § 811. The consequence of such action is that a party may be required to obtain a registration to handle a scheduled substance. 21 U.S.C. § 823; *see MD Pharm.*, 133 F.3d at 13 (the CSA “is a quintessential entry-restricting statute.”). As the Government notes, “[r]esearch of controlled substances is within the class of activity regulated by the CSA.” Gov’t Mot. at 8. Therefore, the zone of interests encompassed by § 811 and the CSA as whole includes researchers who would be regulated by the scheduling of a particular substance.

ANALYSIS

For the following reasons, I find that Panacea, Mindstate, and Tactogen have met the regulatory definition of “interested person” and, thus, have standing to participate in these proceedings.⁴ Ms. Rising, however, does not have standing as an “interested person.” I also reject the Government’s general proposition that an “interested person” may only address a tryptamine if it has established standing for that specific tryptamine.

⁴ While not required, the parties requesting a hearing at issue, with the exception of Ms. Rising, can also show injury-in-fact. In its Partial Withdrawal of its Motion to Dismiss in Part (Government’s Partial Withdrawal), the Government concedes that Tactogen can show injury-in-fact. Gov’t Partial Withdrawal at 1-2. Further, as researchers, Panacea, Mindstate, and Tactogen would suffer economic harm if the tryptamines are scheduled because they would have to obtain a registration to continue their respective projects. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

1. Panacea Plant Sciences

In its RFH and Opposition to the Government's Motion, Panacea, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" its interests in these proceedings.⁵ See Panacea RFH at 3; Panacea Opp'n to Gov't Mot. at 2-3. Specifically, Panacea is a biotech company and has been studying, in collaboration with a Canadian company, the five tryptamines and "other similar compounds in order to treat conditions like depression, anxiety, post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI)." Panacea RFH at 1, 3. Panacea started a project with a doctor at the University of Massachusetts to develop medical therapies utilizing the five tryptamines and other compounds, but Panacea discontinued the project due to the "the potential of conflict and future scheduling." Panacea Opp'n to Gov't Mot. at 2. Additionally, Panacea has patent filings that cover the five tryptamines. *Id.* at 3. Panacea is also collaborating and contracting with other companies and universities to study the five tryptamines and develop therapies, so scheduling the tryptamines will require Panacea to apply for both a manufacturing and research DEA registration. *Id.* at 2-3. Obtaining a registration will be costly for Panacea and cause delays in its research and projects. *Id.*

Panacea meets the regulatory definition of "interested person" under the CSA, as scheduling any or all of the five tryptamines will adversely affect its interests and Panacea's interests fall within the CSA's zone of interests. Panacea falls within the zone of interests because it would be regulated by the scheduling of the five tryptamines; Panacea has ongoing research and projects involving the five tryptamines, and Panacea will be required to obtain a registration to continue its work if the tryptamines are scheduled. See *MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. The potential added cost of obtaining a registration has already forced Panacea to discontinue one project and may require Panacea to discontinue other projects

⁵ The Government argues that Panacea failed to state its interests in its RFH "with particularity," so, if this tribunal does not dismiss Panacea from these proceedings, the tribunal should require Panacea to provide a more detailed statement of its interests. Gov't Mot. at 11. Panacea's RFH provided substantially more detailed information regarding its interests than the two scheduling cases relied on by the Government where the Administrator found that the statements of interest lacked particularity. *Id.* (citing *Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703; *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789). Panacea's Opposition to the Government's Motion further supplemented its statement of interests and provided this tribunal with sufficient information to determine whether Panacea is an "interested person." See Panacea Opp'n to Gov't Mot. at 2-3.

or increase the costs of those projects. Since the purpose of § 811 is to determine whether a substance should be scheduled, thereby bringing the substance under the purview of the CSA and restricting access to it, Panacea's interest in continuing to use the five tryptamines directly relates to the purpose of § 811. Therefore, Panacea has standing in these proceedings.

2. Mindstate and Tactogen

In their joint RFH and Opposition to the Government's Motion, Mindstate and Tactogen, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" their interests in these proceedings.⁶ See Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A. Specifically, Mindstate is a research company that "develops psychedelic drug therapies for intractable mental health conditions" and is "currently investigating one or more of the Five Tryptamines in preclinical research." Mindstate & Tactogen RFH at 2. Mindstate is building a database of phenomenological and biochemical data on psychedelic compounds. Mindstate & Tactogen Opp'n to Gov't Mot. at 3. Mindstate must work with tryptamines to complete this project and other projects to develop and bring compounds to market. *Id.* at 4. Tactogen is a public benefit corporation "developing safer, more effective prescription medicines for mental wellness" and is "currently investigating one or more of the Five Tryptamines as part of a program to develop new medicines." Mindstate & Tactogen RFH at 2. Tactogen has had one published patent application under the Patent Cooperation Treaty on the use of tryptamines for mental disorders. Mindstate & Tactogen Opp'n to Gov't Mot. at 4.

Mindstate and Tactogen each qualify as an "interested person" under the CSA because scheduling any or all of the five tryptamines will adversely affect each of their interests and such interests fall within the zone of interests.⁷ Mindstate and Tactogen fall within the CSA's zone of interests because they would be regulated by the scheduling of the five tryptamines. See *MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. Both companies would

⁶ The Government makes the same argument, as it did with respect to Panacea's RFH, that Mindstate and Tactogen's RFH lacked particularity. See *supra* note 5; Gov't Mot. at 12-13. Mindstate and Tactogen's RFH provided enough detail, and their Opposition to the Government's Motion further supplemented their statement of interests to determine if they are an "interested person." See Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A.

⁷ The Government concedes that Tactogen has established standing with respect to 5-MeO-MiPT. Gov't Partial Withdrawal at 1-2. The Government maintains that Tactogen has still not established standing with respect to the other four tryptamines. *Id.*

be required to obtain registrations to continue their respective projects; Mindstate's development of compounds for mental health conditions and Tactogen's development of therapies for mental wellness would be regulated by the CSA if the five tryptamines are scheduled. Like Panacea, Mindstate and Tactogen's interests in using the tryptamines directly relate to the purpose of § 811. Therefore, Mindstate and Tactogen have standing in these proceedings.

3. Amy Rising

In her RFH, Ms. Rising stated that the proposed scheduling of the five tryptamines "would result in barriers to research and the denial [of] life-saving healthcare to US patients" and that they should be placed in schedule V, not schedule I. Rising RFH at 1-2. In her Opposition to the Government's Motion, Ms. Rising stated that she met with the "senate DEA liaison and senate judiciary counsel at their request to discuss the upcoming renewal of the Fentanyl Analogues" several times between August and December 2019. Rising Opp'n to Gov't Mot. at 1-2. Additionally, the Food and Drug Administration "declared psilocybin a 'breakthrough therapy' for treatment-resistant depression." *Id.* at 1. Ms. Rising further indicated that the "National Institute on Drug Abuse Director" stated that obtaining a schedule I DEA registration is administratively challenging and time consuming, so scientists may be deterred from researching schedule I substances. *Id.* at 2. Ms. Rising concluded that she has interests in the scheduling status of the five tryptamines and placing them in schedule I will "impose greater burdens on research, create barriers to access and impose undue difficulty on policy makers..." *Id.*

Ms. Rising has failed to establish her interest in these proceedings. She has provided no information as to what her specific interest is, such as her career or credentials; rather, she simply asserts that she is interested. *See id.* at 2 ("Amy Rising has provided the example of her work and interests in the scheduling status of" the five tryptamines). The only example she has provided of her work is meetings with government officials regarding psilocybin and the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 S. 3201, 116th Cong. (2020), but she does not explain how the meetings related to the five tryptamines, let alone her role and purpose in those meetings. *See id.* She argues that scheduling the five tryptamines in schedule I will create barriers to research but offers no information as to how or why she is affected by potential barriers for research. *See id.* 2-3.

Ms. Rising's general assertion of interest does not meet the regulatory requirements that she both have an interest in these proceedings and that she state that interest "with particularity."

21 C.F.R §§ 1300.01(b), 1316.47(a); *see Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (denying a request for hearing because a person’s generalized concern was insufficient to demonstrate an interest in the proceeding); *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789 (same). Therefore, given Ms. Rising’s failure to show her interest in these proceedings, she does not have standing to appear in these proceedings.

4. Standing as to Individual Tryptamines

The Government argues that this tribunal should further limit standing in two respects: (1) it should only allow a hearing on those tryptamines for which parties have standing; and (2) an “interested person” should only be allowed to contest a tryptamine for which it has established standing. Gov’t Mot. at 6-7. The Government argues that, while the tryptamines are similar and consolidated into one NPRM, there will be five distinct rules. *Id.* The Government cites no support for the proposition that one NPRM and one rulemaking process results in distinct rules.⁸ Additionally, 21 C.F.R. § 1300.01 defines “interested person” as “any person adversely affected or aggrieved by any rule or proposed rule...” (emphasis added). There is one proposed rule,⁹ not five, so any person adversely affected or aggrieved by the scheduling of one of the tryptamines has standing to challenge the proposed rule in its entirety.

Moreover, the Administrator opted to combine the five tryptamines into one rulemaking process and did so, in part, because of the similarity of those substances to each other and to already-controlled substances. NPRM, 87 Fed. Reg. at 2378. Additionally, the NPRM (as well as the Department of Health and Human Services evaluations and recommendations) includes scientific references that deal generally with tryptamines and compare the substances to each other and already-controlled substances. *Id.* at 2378-81. On this basis, a wholesale limitation of the parties is unjustified and would prove impractical at the merits hearing; it would be incongruous to parse the rulemaking process when the Agency has chosen to proceed under one proposed rule.

⁸ The Government does cite 21 U.S.C. § 811(a)(1); however, § 811(a)(1) provides only that the Attorney General may schedule a substance if he makes findings as to such substance. *See* Gov’t Mot. at 6. Section 811(a)(1) is silent as to standing for an “interested person” to challenge those findings and whether one rulemaking process for multiple substances results in distinct rules or one rule encompassing multiple substances.

⁹ The NPRM also repeatedly states that it is one “proposed action,” not five. *See* NPRM, 76 Fed. Reg. at 2376-78, 2381-82.

Further, even if I were to accept the Government's proposition that each "interested person" must have standing with respect to each tryptamine to fully participate in these proceedings, Panacea, Mindstate, and Tactogen have established standing for all five of the tryptamines. Panacea expressly stated that it is researching the five tryptamines, so scheduling any or all of the tryptamines will adversely affect Panacea. Panacea Opp'n to Gov't Mot. at 2-3. The Government concedes that Tactogen is an "interested person" with respect to 5-MeO-MiPT (Gov't Partial Withdrawal at 1-2), and Mindstate is currently utilizing 5-MeO-MiPT and 4-OH-DiPT (Mindstate & Tactogen Opp'n to Gov't Mot., Ex. A at 2). Both companies are arguably within the zone of interests for the other tryptamines because their research and projects will be limited, as the other tryptamines are analogues or related to hallucinogenic substances that the companies are currently studying. Mindstate & Tactogen Opp'n to Gov't Mot. at 14. In sum, the zone of interests test is not meant to be demanding nor are Mindstate and Tactogen's interests inconsistent with the purpose of § 811. *See Clarke*, 479 U.S. at 399; *MD Pharm.*, 133 F.3d at 12-13. Therefore, I reject the Government's argument to partition the hearing by tryptamine and "interested person."

CONCLUSION

Accordingly, the Government's Motion is **GRANTED IN PART** and **DENIED IN PART**. The Government's Motion is **GRANTED** with respect to Amy Rising and **DENIED** with respect to Panacea, Mindstate, and Tactogen.

Dated: May 6, 2022

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 6, 2022, caused a copy of the foregoing to be delivered to the following recipients:

- (1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
- (2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
- (3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
- (4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
- (5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design;
- (6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com;
- (7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com; and
- (8) Amy Rising, via email at amynicholerising@gmail.com.

Aniayah S. Beckford
Staff Assistant to Judge Wallbaum

- The continued scheduling of cannabis, even at Schedule III, unfairly benefits pharmaceutical companies, limiting access for patients and the general public who could benefit from its therapeutic properties.

- The LaGuardia Committee Report (1944) concluded that marijuana is not addictive, does not lead to the use of harder drugs, and poses no significant social danger. This report challenges the stigma associated with cannabis use. This study indicated that cannabis does not meet the criteria for Schedule I or even Schedule III substances, citing its medical benefits and low potential for abuse.

- The Shafer Commission Report (1972) recommended the decriminalization of personal cannabis use, highlighting the disproportionately harsh penalties imposed under current laws. This study indicated that cannabis does not meet the criteria for Schedule I or even Schedule III substances, citing its medical benefits and low potential for abuse.

- The Medical College of Virginia Study (1974) found that THC, a component of cannabis, could shrink tumors and effectively combat cancer cells. This groundbreaking research underscores the potential therapeutic benefits of cannabis.

- The Institute of Medicine (IOM) Report (1982) emphasized the need for further research into cannabis's medical uses and its potential therapeutic benefits, advocating for a more scientific approach to cannabis policy.

- DEA Administrative Law Judge Francis Young's Ruling (1988) concluded that "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man," recommending its reclassification to facilitate medical use. This ruling challenges the current classification of cannabis as a Schedule I substance.

- The Institute of Medicine Report (1999) acknowledged the medical benefits of cannabis and advocated for continued research to explore its therapeutic potential.

Jasmine Montoya
7893 Wyandot St.
Denver, Co. 80221
Jasmontoyan@gmail

September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Subject: Request for Hearing and Waiver -

Document Type: Proposed Rule
Document Citation: 89 FR 44597
Page: 44597-44622 (26 pages)
CFR: 21 CFR 1308
Agency/Docket Numbers: Docket No. DEA-1362
A.G. Order No.: 5931-2024
Document Number: 2024-11137

To Whom It May Concern,

We are writing to formally request a hearing and submit a waiver in connection with the regulatory proceedings referenced above. We assert our position on the matters of fact and law as outlined below and seek the opportunity to present our case before the appropriate authorities.

Statement of Position:

- Matters of Fact:

- The proposed rescheduling of cannabis from Schedule I to Schedule III does not adequately address the systemic issues and historical injustices associated with its classification.

- The World Health Organization (WHO) Recommendations (2019) suggested the international rescheduling of cannabis and its derivatives due to medical benefits and lower risk profiles compared to other Schedule I substances, highlighting global recognition of cannabis's medicinal value.

- Nixon Administration: In the 1970s, President Richard Nixon commissioned studies on cannabis, including the Medical College of Virginia Study, which found promising medical uses for THC. Despite these findings, Nixon dismissed the research and escalated the War on Drugs, perpetuating misinformation about cannabis.

- Reagan Administration: During the 1980s, the Reagan administration ignored recommendations from the Institute of Medicine and other scientific bodies advocating for further research into cannabis's medical benefits. Policies during this era reinforced strict anti-cannabis laws and hindered scientific progress.

2. Matters of Law:

- These historical and scientific findings challenge the basis for current cannabis scheduling under the Controlled Substances Act (21 CFR 1308). The evidence presented supports the argument for reconsidering the scheduling of cannabis to reflect its therapeutic potential and societal impact accurately.

We believe that a hearing is necessary to ensure a fair and thorough examination of these issues. We respectfully request that the DEA schedule a hearing at the earliest convenience to address these matters.

For informational purposes, We are also sending courtesy copies of this request for hearing and waiver to the following addresses:

1. Drug Enforcement Administration

Attn: Hearing Clerk/OALJ
8701 Morrisette Drive
Springfield, Virginia 22152

2. Drug Enforcement Administration

Attn: DEA Federal Register Representative/DPW



8701 Morrisette Drive
Springfield, Virginia 22152

Thank you for your attention to this request. We look forward to your response and the opportunity to present our case.

Sincerely,

Jasmine Montoya

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ, or Administrator
8701 Morrisette Dr., Springfield, VA 22152.
nprm@dea.gov

Subject: Notice of Appearance

Dear Sir/Ma'am:

Please take notice that Mr. Jason Greninger will appear in the matter of: Docket No. DEA-1362.

(A) An administrator, researcher, data analyst, and career patient advocate and Legislative & Congressional Outreach Coordinator for CPR/CC Coalition for Patients Rights / Compassion Center, a pioneering medical management services organization (MSO), and (CBCCERN) Community-Based Clinical Cannabis Evaluation & Research Network and the Center for Incubation & Findings Research (CIFR)

CBCCERN serves as the first-of-its kind platform to provide organization, administration and oversight on organized peer-reviewed research of the cannabis plant, its various individual compounds and various preparations, through National networks of (Endo)Cannabinologists, Researchers and Licensed Clinicians who are also currently in the practice of recommending medical cannabis for the treatment and alleviation of disorders that are not well addressed by existing FDA-approved therapies. Today, CBCCERN is under the Compassion Center and the Center for Incubation & Findings Research where it leads a variety of outreach and clinical efforts related to widespread adoption of its network. A major part of the Teach1Serve10.org Free Clinic System, CBCCERN trains, manages and oversees the medical cannabis clinical practicums, medical cannabis recommendations and registration with the state, credentialing, patient advocacy and interprofessional continuing medical education development organization focusing on expanding patient access to medical cannabis, and based in Oregon. As the oldest medical cannabis clinic still in existence, Compassion Center has been at the forefront of improving the quality of life for medical cannabis patients by facilitating access to state-managed programs since June of 2001. Today, Compassion Center's providers evaluate patients, and subsequently provide qualifying patients with recommendations, referrals and/or registrations for states that medical cannabis is authorized under law and currently supports expanding medical cannabis programs in 18 states.

Our efforts have directly guided over 15,000 Oregonians in reducing their dependence on opioid pain management and alleviating intractable neurological conditions, and have since assisted a countless number of others across the U.S. through continuing medical education and referrals, and as previously stated, we even provide clinical access to patients in eighteen states. Drawing from this extensive experience, we will provide critical insights, data, and professional opinions on the current state of the cannabis industry, product purity standards, patient safety issues and diversion into the illicit "black" market. Additionally, we will address potential impacts of cannabis rescheduling, offering unique perspectives that can help the DEA, and any other government agencies, protect our patients, providers, facilities and institutions effectively, while maintaining a wide range of liberties and justice for all Americans.

(B) Cannabis has literally been used for thousands of years as G.R.A.S. (Generally Regarded As Safe), for animal feed and as medicine, but never before have farmers had access to, nor the desire to use chemical additives in the production of their crops.. However, due a variety of factors ranging from a diminishing agricultural workforce and depleted soils to otherwise predatorial and often deceptive marketing practices in the agricultural industry regarding genetically modified crops, chemicals, pesticides, additives and/or hormones, leading farmers to achieve "easy ways to amplify yields", we face a myriad of concerning factors with regards to purity, safety, potency and efficacy. In the recreational cannabis space, specifically, plant growth regulators (PGRs) are regularly used to regulate and manipulate cellular processes in the plant cells that are targeted, in order to boost their yields. PGRs have evidently become an issue for medical cannabis patients as their cannabis farmers are becoming more and more dependent upon the technology and less dependent upon the land, permaculture and people. It is therefore a constitutional issue on the personal access to a simple plant that was previously; and by all current definitions, designated as G.R.A.S. (Generally Regarded As Safe)

(C) 1) Discussion of supportive testimony to add to this hearings evidence include, congressional records of the committee discussions with the AMA regarding the marijuana Act prior to the vote, the congressional records of the floor discussions regarding the AMA prior to the vote, congressional records specific to the DEA, DOJ, and cannabis/marijuana, and U.S. patents records regarding cannabinoids.

2) Supportive of responsible descheduling as cannabis fits within all FDA requirements and definitions of G.R.A.S. and designated as evidence; and as such historically and by the current FDA rules for G.R.A.S use before 1958; thus taking a variety of considerations into account in order for allopathic, integrative and traditional health practitioners, and other pharmaceutical industry stakeholders to safely integrate the cannabis plant into the continuum of care, further protecting cannabis patients by preventing the plants from being adulterated or isolated in ways that either reduce efficacy or create safety issues that must be addressed in emergency rooms.

All notices to be sent pursuant to this appearance should be addressed to:

Compassion Center
% James Creel, PgM
P.O. Box 868
Clackamas, OR 97015

Respectfully yours


Jason Greninger

CPR/CC Legislative & Congressional Outreach Coordinator
Compassion-Center.org
Jason.Greninger@MyCPR.US
702-401-8620

**Intent to testify at Dec 2 hearing in DC
regarding Descheduling/ rescheduling
of cannabis.**

To whom it may concern, my name is Jordan Smith, I would like to express my intent to testify at the December 2nd hearing regarding the descheduling/ rescheduling of cannabis.

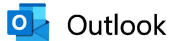
I strongly support the descheduling of cannabis and believe that rescheduling will cause much more harm than good to the American people.

There are several reasons I support descheduling and I will touch briefly on those here.

- **Rescheduling will bring with it a new wave of prohibition as possession and manufacture of schedule III substances is highly regulated.** Currently with the help of the Cole memo and the Rothburg Farr amendment individuals in legal states have more protection now than they will under schedule III. Rescheduling will create millions of “criminals” out of innocent people.
- **Schedule III will effectively hand over the industry to pharmaceutical companies who have a very poor track record of having the best interest of consumers in mind.** Under their control prices will skyrocket and the black market will proliferate and become the primary source of cannabis thus having the opposite of the intended effect of rescheduling.
- We still have 35,000 individuals in prison for non violent cannabis crimes. We will have more under schedule III. This is the opposite of what needs to happen.
- **This is not a new industry**, on the state level large corporations and state regulators are already pushing out small producers via regulatory capture, overzealous regulation that small operators simply cannot afford to adhere to. These are the people who put there life and freedom on the line to even be in a place that we are having this discussion. We already are seeing many monopoly States where the legislation has pushed out all smaller operators before the programs even launch, in these states we see hyper inflated prices and low quality, unsafe products in the legal market. The stake held in the industry by small operators must be preserved by any means possible. They ARE this industry. Appropriation by mega corporations and the pharmaceutical industry is not an option. There must be a clear path with low hurdles for these individuals and companies to continue their work.

Thank you for your time and consideration.

My Very Best,
Jordan Smith
207-939-3093



Outlook

[EXTERNAL] Docket No. DEA- 1362

From Karen O'Keefe <kokeefe@mpp.org>**Date** Mon 9/30/2024 4:59 PM**To** NPRM <NPRM@dea.gov>

2 attachments (278 KB)

Docket No DEA- 1362 DEA Hearing Request to Appear MPP.pdf; Reiman CV.2024.pdf;

Dear Drug Enforcement Administration Administrator:

The

Marijuana Policy Project hereby requests to appear as an interested party at the hearing in the matter of: Docket No. DEA-1362, "Schedules of Controlled Substances: Rescheduling of Marijuana."

(1)**State with particularity the interest of the person in the proceeding:**

The Marijuana Policy Project is

a non-profit organization that believes adults and patients who could benefit from botanical marijuana ("cannabis") should be allowed to use and safely access it. MPP has more than 300,000 email alert subscribers and thousands of members, many of whom find

relief from the medical use of cannabis. MPP supports the DEA reclassifying botanical marijuana from Schedule I to Schedule III, although it would be more appropriate to deschedule marijuana.

MPP was founded in 1995 and has

played a significant role in enacting 15 state medical cannabis laws. It compiles educational information on medical cannabis policies and laws, many of which are available at its website at mpp.org.

Director of State Policies Karen

O'Keefe has worked at MPP since 2003, leading MPP's work both in enacting many of those laws and analyzing those laws for informational materials summarizing those laws. She is an attorney

who is licensed in Washington, D.C., and an expert on state cannabis policy.

MPP also offers as an expert witness

Amanda Reiman, PhD, MSW, whose CV is attached. Amanda Reiman, PhD is the Chief Knowledge Officer for New Frontier Data. New Frontier Data uses multiple datasets to create actionable insights for licensed cannabis businesses in the areas of customer acquisition, sales trends, market modeling, and consumer behavior. Dr. Reiman earned her PhD in Social Welfare from the University of California and conducted one of the first research studies on medical cannabis patients and the use of cannabis as a substitute for alcohol and other drugs. Having studied cannabis use and policy for over 20 years, she is an internationally recognized cannabis expert and public health researcher. Formerly the in-house cannabis expert for the Drug Policy Alliance, she has written for/been quoted in numerous national and international publications as well as peer-reviewed academic journals and several textbooks. She was the first Chairwoman for the Berkeley Medical Cannabis Commission and a commissioner for the Oakland Cannabis Regulatory Commission.

(2)

State with particularity the objections or issues concerning which the person desires to be heard:

MPP

would like to participate in the rescheduling hearing in a general capacity as an advocacy organization that has worked with numerous patients, medical professionals, and health and medical organizations to allow the medical use of cannabis and to advance research.

In

addition to general participation, MPP wishes to be heard on the following issues:

a.

HHS's basis for its recommendations says 38 states and four U.S. territories have enacted medical cannabis laws since 1996. (HHS Basis for Rec. at 30) This understates the number of states that have departed from federal policy on medical cannabis.

b.

The non-problematic, independent use of cannabis should not be conflated with “abuse.” HHS includes as a factor for determining if a drug has potential for abuse, “Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.” (HHS Basis for Rec. at 6)

c.

Some have suggested DEA should revert back to the five-part test for CAMU that was developed in 1992 and based on FDCA standards. MPP requests to be heard on the issue if the DEA considers those arguments.

(3)

State briefly the position of the person regarding the objections or issues.

a.

While MPP counts the number of states with comprehensive medical cannabis laws as 38, at least seven additional states have more limited laws that allow the medical use of botanical cannabis preparations with more than 0.3% THC: Georgia, Iowa, Kansas, North Carolina, South Carolina, Tennessee, and Texas. Three of those states — Texas, Iowa, and Georgia — allow the in-state production and sale of cannabis preparations to qualifying patients with a healthcare practitioner’s certification. Between now and the hearing, one more state, Nebraska, may join the ranks, as companion medical cannabis ballot initiatives were certified for the November 5, 2024, ballot.

In

addition, three states will be considering adult-use cannabis legalization before the hearing — Florida, North Dakota, and South Dakota. If all three pass, the total number of adult-use legal states would be 27, home to more than 60% of the U.S. population.

b.

According to Merriam-Webster, "abuse" is "improper or excessive use." The non-problematic, self-initiated use of cannabis should not be considered in assessing cannabis' potential for abuse. Studies have shown a significant percent of adult-use cannabis users are using it as an over-the-counter medication. For many, cannabis use is not only not problematic, it's beneficial. Surveys show a significant portion of cannabis users who were previously using alcohol and opiates reduce their use of those more risky substances.

Moreover,

the majority of Americans live in one of the 24 states where cannabis is legal under state law for adults 21 and older, whether it is for over-the-counter medical use or for "recreational" use. According to Gallup, 70% of Americans support making marijuana use legal.

(c) HHS rightly abandoned the

five-part test that the DEA developed in 1992, which strayed impermissibly from the language of 21 U.S.C. § 812(b). As the Office of Legal Counsel noted, "DEA's approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard." Reverting to the five-part test would also run afoul of the June 28, 2024, Supreme Court decision,

Loper

Bright Enterprises v. Raimondo,

which overturned *Chevron's*

"broad rule of deference" to agencies.

The

CSA and the FDCA are separate laws on different topics, enacted at different times. Taking the definition for FDA approval from FDCA and injecting it into CSA as a definition of "accepted medical use" is a misinterpretation of the plain language of the statutes.

In

addition to MPP Director of State Policies Karen O'Keefe and Dr. Amanda Reiman, MPP is prepared to proffer additional witnesses on issues including cannabis' currently accepted medical use, its relative potential for abuse, and criminal justice impacts.

Thank
you for your work on this important matter.

Sincerely,

 KOKeefe

Karen
O'Keefe

Director
of State Policies

Marijuana
Policy Project & MPP Foundation

2370
Champlain, NW #12

Washington,
D.C. 20009

kokeefe@mpp.org

202-905-2012

**Appendix: Written
Statement of Position on the Matters of Fact and Law**

**Docket No. DEA-
1362 — Marijuana Policy Project**

As

further explained in MPP's comment (DEA-2024-0059-39926), MPP agrees with the conclusion that botanical marijuana (also known as cannabis) does not meet the criteria as a Schedule I or Schedule II drug. Schedule I drugs must have "no currently accepted medical use in treatment in the United States," a high potential for abuse, and there must be "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b). Cannabis does not meet any of those criteria.

Cannabis'

medical value is almost universally acknowledged by U.S. states, as is its lower potential for abuse than Schedule II drugs, including prescription opioids.

Regarding

the three issues outlined in this request to be heard:

a.

CAMU: At least 41 states allow the production and medical use of botanical marijuana preparations.

States

have almost universally acknowledged that botanical cannabis has medical value. In addition to the 38 states that MPP considers to have "comprehensive" medical cannabis laws,

Texas, Georgia,

and Iowa have programs

allowing the production, distribution, and medical use of lower-THC cannabis preparations to patients with a healthcare professional's certification. Additional states have enacted laws allowing the possession of some federally illegal low-THC cannabis products

for medical use, including North Carolina, South Carolina, and Tennessee.

b.

Independent cannabis use is not “abuse.”

According

to Merriam-Webster, “abuse” is “improper or excessive use.”

The non-problematic, self-initiated use of cannabis should not be considered in assessing cannabis’ potential for abuse. Studies have shown a significant percent of adult-use cannabis users are using it as an over-the-counter medication.

For many, cannabis use is not only not problematic, it’s beneficial. Surveys show a significant portion of cannabis users who were previously using opiates are able to reduce their use of those more risky medications.

Moreover,

the majority of Americans live in one of the 24 states where cannabis is legal under state law for adults 21 and older, whether it is for over-the-counter medical use or for “recreational” use.

According to Gallup, 70% of Americans support making marijuana use legal.

(c)

The DEA’s five-part test was rightly abandoned to conform to the plain language of 21 U.S.C. § 812.

HHS

rightly abandoned the five-part test that the DEA developed in 1992, which strayed impermissibly from the language of 21 U.S.C. § 812(b). As the Office of Legal Counsel noted, “DEA’s approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard.”

Reverting to the five-part test would be particularly problematic in light of the June 28, 2024, Supreme Court decision,

Loper

Bright Enterprises v. Raimondo,

which overturned *Chevron’s*

“broad rule of deference” to agencies.

The

CSA and the Federal Food, Drug, and Cosmetic Act (FDCA) are separate laws on different topics, enacted at different times. The CSA was enacted in 1970, nearly four decades after the 1938 FDCA.

Congress could have adopted the FDCA standard for scheduling. It did not.

Taking
the definition for FDA approval from FDCA and injecting it into CSA as a definition of "accepted medical use" ignores the plain meaning of the statutes.



Marijuana Policy Project
P.O. Box 21824 • Washington, DC 20009
202-462-5747 • www.mpp.org

September 30, 2024

Re: Docket No. DEA- 1362

Sent via email nprm@dea.gov

Dear Drug Enforcement Administration Administrator:

The Marijuana Policy Project hereby requests to appear as an interested party at the hearing in the matter of: Docket No. DEA-1362, "Schedules of Controlled Substances: Rescheduling of Marijuana."

(1) State with particularity the interest of the person in the proceeding:

The Marijuana Policy Project is a non-profit organization that believes adults and patients who could benefit from botanical marijuana ("cannabis") should be allowed to use and safely access it. MPP has more than 300,000 email alert subscribers and thousands of members, many of whom find relief from the medical use of cannabis. MPP supports the DEA reclassifying botanical marijuana from Schedule I to Schedule III, although it would be more appropriate to deschedule marijuana.

MPP was founded in 1995 and has played a significant role in enacting 15 state medical cannabis laws. It compiles educational information on medical cannabis policies and laws, many of which are available at its website at mpp.org.

Director of State Policies Karen O'Keefe has worked at MPP since 2003, leading MPP's work both in enacting many of those laws and analyzing those laws for informational materials summarizing those laws. She is an attorney who is licensed in Washington, D.C., and an expert on state cannabis policy.

MPP also offers as an expert witness Amanda Reiman, PhD, MSW, whose CV is attached. Amanda Reiman, PhD is the Chief Knowledge Officer for New Frontier Data. New Frontier Data uses multiple datasets to create actionable insights for licensed cannabis businesses in the areas of customer acquisition, sales trends, market modeling, and consumer behavior. Dr. Reiman earned her PhD in Social Welfare from the University of California and conducted one of the first research studies on medical cannabis patients and the use of cannabis as a substitute for alcohol and other drugs. Having studied cannabis use and policy for over 20

years, she is an internationally recognized cannabis expert and public health researcher. Formerly the in-house cannabis expert for the Drug Policy Alliance, she has written for/been quoted in numerous national and international publications as well as peer-reviewed academic journals and several textbooks. She was the first Chairwoman for the Berkeley Medical Cannabis Commission and a commissioner for the Oakland Cannabis Regulatory Commission.

(2) State with particularity the objections or issues concerning which the person desires to be heard:

MPP would like to participate in the rescheduling hearing in a general capacity as an advocacy organization that has worked with numerous patients, medical professionals, and health and medical organizations to allow the medical use of cannabis and to advance research.

In addition to general participation, MPP wishes to be heard on the following issues:

- (a) HHS's basis for its recommendations says 38 states and four U.S. territories have enacted medical cannabis laws since 1996. (HHS Basis for Rec. at 30) This understates the number of states that have departed from federal policy on medical cannabis.
- (b) The non-problematic, independent use of cannabis should not be conflated with "abuse." HHS includes as a factor for determining if a drug has potential for abuse, "Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice." (HHS Basis for Rec. at 6)
- (c) Some have suggested DEA should revert back to the five-part test for CAMU that was developed in 1992 and based on FDCA standards. MPP requests to be heard on the issue if the DEA considers those arguments.

(3) State briefly the position of the person regarding the objections or issues.

- (a) While MPP counts the number of states with comprehensive medical cannabis laws as 38, at least seven additional states have more limited laws that allow the medical use of botanical cannabis preparations with more than 0.3% THC: Georgia, Iowa, Kansas, North Carolina, South Carolina, Tennessee, and Texas. Three of those states — Texas, Iowa, and Georgia — allow the in-state production and sale of cannabis preparations to qualifying patients with a healthcare practitioner's certification. Between now and

the hearing, one more state, Nebraska, may join the ranks, as companion medical cannabis ballot initiatives were certified for the November 5, 2024, ballot.

In addition, three states will be considering adult-use cannabis legalization before the hearing — Florida, North Dakota, and South Dakota. If all three pass, the total number of adult-use legal states would be 27, home to more than 60% of the U.S. population.

- (b) According to Merriam-Webster, "abuse" is "improper or excessive use." The non-problematic, self-initiated use of cannabis should not be considered in assessing cannabis' potential for abuse. Studies have shown a significant percent of adult-use cannabis users are using it as an over-the-counter medication. For many, cannabis use is not only not problematic, it's beneficial. Surveys show a significant portion of cannabis users who were previously using alcohol and opiates reduce their use of those more risky substances.

Moreover, the majority of Americans live in one of the 24 states where cannabis is legal under state law for adults 21 and older, whether it is for over-the-counter medical use or for "recreational" use. According to Gallup, 70% of Americans support making marijuana use legal.

- (c) HHS rightly abandoned the five-part test that the DEA developed in 1992, which strayed impermissibly from the language of 21 U.S.C. § 812(b). As the Office of Legal Counsel noted, "DEA's approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard." Reverting to the five-part test would also run afoul of the June 28, 2024, Supreme Court decision, *Loper Bright Enterprises v. Raimondo*, which overturned *Chevron's* "broad rule of deference" to agencies.

The CSA and the FDCA are separate laws on different topics, enacted at different times. Taking the definition for FDA approval from FDCA and injecting it into CSA as a definition of "accepted medical use" is a misinterpretation of the plain language of the statutes.

In addition to MPP Director of State Policies Karen O'Keefe and Dr. Amanda Reiman, MPP is prepared to proffer additional witnesses on issues including cannabis' currently accepted medical use, its relative potential for abuse, and criminal justice impacts.

Thank you for your work on this important matter.

Sincerely,

A handwritten signature in black ink that reads "Karen O'Keefe". The signature is fluid and cursive, with the first name "Karen" and last name "O'Keefe" clearly distinguishable.

Karen O'Keefe
Director of State Policies
Marijuana Policy Project & MPP Foundation
2370 Champlain, NW #12
Washington, D.C. 20009
kokeefe@mpp.org
202-905-2012

Appendix: Written Statement of Position on the Matters of Fact and Law Docket No. DEA- 1362 — Marijuana Policy Project

As further explained in MPP's comment (DEA-2024-0059-39926), MPP agrees with the conclusion that botanical marijuana (also known as cannabis) does not meet the criteria as a Schedule I or Schedule II drug. Schedule I drugs must have "no currently accepted medical use in treatment in the United States," a high potential for abuse, and there must be "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b). Cannabis does not meet any of those criteria.

Cannabis' medical value is almost universally acknowledged by U.S. states, as is its lower potential for abuse than Schedule II drugs, including prescription opioids.

Regarding the three issues outlined in this request to be heard:

(a) CAMU: At least 41 states allow the production and medical use of botanical marijuana preparations.

States have almost universally acknowledged that botanical cannabis has medical value. In addition to the 38 states that MPP considers to have "comprehensive" medical cannabis laws,¹ Texas,² Georgia,³ and Iowa⁴ have programs allowing the production, distribution, and medical use of lower-THC cannabis preparations to patients with a healthcare professional's certification. Additional states have enacted laws allowing the possession of some federally illegal low-THC cannabis products for medical use, including North Carolina, South Carolina, and Tennessee.⁵

¹ Those states are: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Virginia, Washington, and West Virginia. Washington D.C. and these four U.S. territories also have medical cannabis laws MPP considers "comprehensive" Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands. See: <https://www.mpp.org/issues/medical-marijuana/key-aspects-of-state-and-dc-medical-marijuana-laws/> and <https://www.mpp.org/policy/us-territories/>

² See: <https://www.texas.gov/health-services/texas-medical-marijuana/>

³ See: <https://dph.georgia.gov/low-thc-oil-registry>

⁴ See: <https://hhs.iowa.gov/programs/programs-and-services/medical-cannabis>

⁵ N.C.G.S.A. § 90-94.1 (patients with intractable epilepsy can use hemp extracts with at least 5% CBD and less than 0.9% THC), S.C. Code 1976 § 44-53-110 (27)(b-d)(Patients with Lennox Gastaut Syndrome, Dravet Syndrome, or "any other severe form of epilepsy that is not adequately treated by traditional medical therapies" may use cannabis products that contains 0.9% or less THC and over 15% CBD with their doctor's certification), T.C.A. § 39-17-402 (16) (F) (Patients with intractable seizures can use cannabis oil with less than 0.9% of THC if it was obtained pursuant to a "legal order or recommendation from the issuing state")

(b) Independent cannabis use is not “abuse.”

According to Merriam-Webster, “abuse” is “improper or excessive use.”⁶ The non-problematic, self-initiated use of cannabis should not be considered in assessing cannabis’ potential for abuse. Studies have shown a significant percent of adult-use cannabis users are using it as an over-the-counter medication.⁷ For many, cannabis use is not only not problematic, it’s beneficial. Surveys show a significant portion of cannabis users who were previously using opiates are able to reduce their use of those more risky medications.⁸

Moreover, the majority of Americans live in one of the 24 states where cannabis is legal under state law for adults 21 and older, whether it is for over-the-counter medical use or for “recreational” use.⁹ According to Gallup, 70% of Americans support making marijuana use legal.¹⁰

(c) The DEA’s five-part test was rightly abandoned to conform to the plain language of 21 U.S.C. § 812.

HHS rightly abandoned the five-part test that the DEA developed in 1992, which strayed impermissibly from the language of 21 U.S.C. § 812(b). As the Office of Legal Counsel noted, “DEA’s approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard.”¹¹ Reverting to the five-part test would be particularly problematic in light of the June 28, 2024, Supreme Court decision, *Loper Bright Enterprises v. Raimondo*, which overturned *Chevron’s* “broad rule of deference” to agencies.

⁶ <https://www.merriam-webster.com/dictionary/abuse> (2)

⁷ See: Bachhuber M, Arnsten JH, Wurm G. Use of Cannabis to Relieve Pain and Promote Sleep by Customers at an Adult Use Dispensary. *J Psychoactive Drugs*. 2019 Nov-Dec;51(5):400-404. doi: 10.1080/02791072.2019.1626953. Epub 2019 Jul 2. PMID: 31264536; PMCID: PMC6823130.; New Frontier Data Consumer Survey, (“40% of consumers say their use is primarily or only medical”); Amanda Reiman Ph.D., MSW), “Necessity vs. Nicety: Adult-use and medical patient spending during tough economic times,” New Frontier Data, January 10, 2023.

⁸ Bachhuber et al, : Use of Cannabis to Relieve Pain and Promote Sleep by Customers at an Adult Use Dispensary, ““Among respondents taking cannabis for pain, 80% reported that it was very or extremely helpful, and most of those taking over-the-counter pain medications (82%) or opioid analgesics (88%) reported reducing or stopping use of those medications.”; Kevin F. Boehnke, J. Ryan Scott, Marc O. Martel, Tristin Smith, Rachel S. Bergmans, Daniel J. Kruger, David A. Williams, Mary-Ann Fitzcharles “Substituting Medical Cannabis for Medications Among Patients with Rheumatic Conditions in the United States and Canada,” *ACR Open Rheumatology* 05 September 2024 <https://doi.org/10.1002/acr2.11717>

⁹ Athena Chapekis and Sono Shah, “Most Americans now live in a legal marijuana state – and most have at least one dispensary in their county” Pew Research Center, February 29, 2024.

¹⁰ Lydia Saad, “Grassroots Support for Legalizing Marijuana Hits Record 70%,” Gallup, November 8, 2023.

¹¹ www.dea.gov/sites/default/files/2024-05/2024-04-11%20-%20AAG%20Fonzone%20-%20Marijuana%20Rescheduling.pdf

The CSA and the Federal Food, Drug, and Cosmetic Act (FDCA) are separate laws on different topics, enacted at different times. The CSA was enacted in 1970, nearly four decades after the 1938 FDCA. Congress could have adopted the FDCA standard for scheduling. It did not.

Taking the definition for FDA approval from FDCA and injecting it into CSA as a definition of "accepted medical use" ignores the plain meaning of the statutes.

CURRICULUM VITAE AMANDA REIMAN**Date:** 1/31/2024**SURNAME:** Reiman**FIRST NAME:** Amanda**MIDDLE NAME(S):** Elizabeth**POST-SECONDARY EDUCATION**

| University or Institution | Degree | Subject Area | Dates |
|--|--------|---|---------------------|
| University of California, Berkeley | PhD | Social Welfare | 08/2002-05/2006 |
| Jane Addams College of Social Work, University of Illinois, Chicago | MSW | Social Work: Community and Administrative Practice | 08/2000-05/2002 |
| University of Illinois, Chicago | BA | Psychology | 01/1998- 05/2000 |

Title of Dissertation and Name of Supervisor*Cannabis Care: Medical Cannabis Facilities as Health Service Providers*

Supervisor: Lorraine Midanik, Ph.D.

EMPLOYMENT RECORD

| University, Company or Organization | Rank or Title | Dates |
|--|---------------------------------------|---------------------|
| New Frontier Data | Chief Knowledge Officer | 1/2021-present |
| Excelsior College | Instructor | 09/2021-present |
| Flow Cannabis Company | VP, Community Development | 02/2017- 11/2020 |
| Drug Policy Alliance | Manager, Marijuana Law and Policy | 01/2012- 1/2017 |
| Humboldt State University School of Social Work | Lecturer | 08/2012- 05/2013 |
| University of California, Berkeley School of Social Welfare | Lecturer | 05/2005- 05/2017 |
| Berkeley Patients Group | Head of Research and Patient Services | 12/2009- 12/2011 |
| University of California, Berkeley School of Social Welfare | Academic Coordinator | 8/2008-12/2009 |
| Alcohol Research Group School of Public Health, UC Berkeley | Pre- and Post-Doctoral Fellowships | 8/2005-5/2008 |

TEACHING*Courses Taught at University of California, Berkeley and UC Extension¹*

SW110: Social Work as a Profession (undergrad)

SW148/SW250: Substance Abuse Treatment (undergrad and graduate)

SW116: Sexuality and Social Work (a class I developed myself, undergrad)

SW238B: Drug and Alcohol Policy (graduate)

SW282A/B: Research Methods (graduate)

Medical cannabis in California (continuing education)¹

Courses Taught at Humboldt State University

SW582/583: Research Methods (graduate, online course)

*Honors in Teaching***UC Berkeley School of Social Welfare**

Graduate Student Instructor of the Year/2006

Undergraduate Lecturer of the Year/2009

Students for Sensible Drug Policy

Lifetime Achievement Award/2017

SCHOLARLY AND PROFESSIONAL ACTIVITIES*Areas of special interest and accomplishments***Cannabis use; harm reduction; evidence informed practice; research methods; community-based practice; drug policy***Research or equivalent grants and contracts*

| Granting Agency | Subject | Year | Principal Investigator |
|---|--|-------------|-------------------------------|
| National Institute of Health | Pre- and post-doctoral fellowships through an NIH Training Grant on Alcohol Problems | 2005-2008 | Lee Kaskutas |
| National Institute on Alcohol and Alcoholism | Time-Series analysis of alcohol use and related problems | 2007 | Bill Kerr |
| National Alcoholic Beverage Control Association | Alcohol Policy Research and Alcoholic Beverage Control Systems: Annotated Bibliography & Review | 2007-2008 | Bill Kerr |
| Berkeley Patients Group | Cannabis as a substitute for alcohol and other drugs | 2008 | Amanda Reiman |
| SPARC | Cannabis and meditation as harm reduction for methamphetamine use | 2012 | Amanda Reiman |
| Research Triangle International | Budtender education and customer facing behavior | 2017 | Nicholas Pieper |
| Hello MD/Kent State University | Cannabis as a substitute for opiates | 2017 | Amanda Reiman |
| National Institute of Health. University of California, San Francisco | Cannabis and other drug use among breastfeeding women and interactions with health care providers. | 2018- | Katie Woodruff |
| National Institute of Health. University of California, San Francisco | Second-hand cannabis smoke and public health | 2019- | Suzaynn Schick |
| National Institute on Drug Abuse. University of California, San Francisco | The development of a self-report measure of THC consumption in the general population | 2020 | Suzaynn Schick |
| State of California: University of California, Berkeley | Licensed and Unlicensed Cultivation Across Ban and Permit Jurisdictions | In Process | Van Butsic |

COMMUNITY PRACTICE*Areas of special interest and accomplishments*

I have been fortunate and have had the opportunity to practice community social work across a number of fields: education, social policy, harm reduction, community empowerment and workforce development.

Early in my career, I developed a budtender training program based on a client-centered social work approach. At the time, many of the people accessing dispensaries were seriously ill, yet those who worked there were not versed in how to approach those with illness. This training was then required by Washington D.C. in the licensing of their earliest dispensaries. In addition to budtender training, I developed and taught a course on medical cannabis for women recently diagnosed with cancer at the Women's Cancer Resource Center in Oakland, and for older adults at a retirement community in the Bay Area of CA.

Social policy development and reform has also played a large role in my community practice. In addition to sitting on two municipal cannabis regulatory commissions, I helped develop the first cannabis equity program in the country in the city of Oakland, CA and, in addition to being a drafter, was the public face and community organizer for the campaign to legalize cannabis in CA in 2016, Proposition 64.

I currently live in a rural area in Northern California, which has provided a landscape for work in harm reduction, community empowerment and workforce development. Through my work on the Drug Free Communities Coalition, I was able to bring a harm reduction-based drug education curriculum to the local school system. I also created and presented a free grant writing workshop at our local tribal health facility, focused on Native American organizations. Finally, I am currently working with our county and state to develop a cannabis apprenticeship program with the local community college to facilitate workforce development in our small community.

Memberships on commissions and boards including offices held and dates

| | |
|---------|--|
| 2020- | Member – Industrial Advisory Committee, Excelsior College Cannabis Program (NY) |
| 2018-21 | Board Member – California Cannabis Tourism Association (CA) |
| 2018-20 | Member - Drug Free Communities Steering Committee (CA) |
| 2017-18 | Secretary and Founding Board Member - International Cannabis Farmers' Association (CA) |
| 2016 | Member – McNeill Institute/Washington Office on Latin America Cannabis Legalization and the Public Health Working Group (DC) |
| 2015-17 | Commissioner – Cannabis Regulatory Commission, City of Oakland, CA (CA) |
| 2010-13 | Chair, Distribution Committee – American Herbal Products Assoc. Cannabis Group (US) |
| 2009-10 | Member - Committee to develop a joint MSW/MPP program, UC Berkeley (CA) |
| 2008-10 | Chair – Medical Cannabis Commission, City of Berkeley, CA (CA) |

Reviewer

| | |
|--------|---|
| 2008 - | Ad hoc reviewer: <i>Addiction; Addictive Behavior; Cannabis and Cannabinoid Research; Harm Reduction Journal; International Journal of Drug Policy; Journal of Drug and Alcohol Dependence; Journal of Community Mental Health; Substance Abuse Treatment, Prevention and Policy</i> |
|--------|---|

PUBLICATIONS RECORD

JOURNAL ARTICLES

Reiman, A. (2007). Patient Profiles: Medical cannabis patients and health care utilization patterns. *Complementary Health Practice Review*, 12(1), 31-50.

Reiman, A. (2008). Self-efficacy, social support and service integration at medical cannabis facilities in the San Francisco Bay area of California. *Health and Social Care in the Community*, 16(1), 31-41.

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Reiman, A. (2009). Moral Philosophy and Social Work Policy. *Journal of Social Work Values and Ethics*, 6(3): <http://www.social-worker.com/jswve/content/view/136/69/>.

Gambrill, E. and **Reiman, A.** (2011). A Propaganda Index for Reviewing Articles and Manuscripts: An Exploratory Study. *PLoS ONE* 6(5):e19516. doi:10.1371/journal.pone.0019516.

Janicheck, J. and **Reiman, A.** (2012). Clinical Service Desires of Medical Cannabis Patients. *Harm Reduction Journal*, 9:12.

Lucas, P., **Reiman, A.** and Earleywine, M. (2013). Cannabis as a substitute for alcohol and other drugs: A dispensary-based survey of substitution effect in Canadian medical cannabis patients. *Journal of Addiction Theory and Research*. DOI: 10.3109/16066359.2012.733465.

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Reiman, A., Aggarwal, S. and Reinerman, C. (2014). Medicalization of Marijuana. *JAMA*, 312(18): 1931.

Reiman, A., Earlywine, M. and Corva, D. (2014). Rethinking dose-response effects of cannabis use in adolescence. *Lancet Psychiatry*, 1(6): DOI: 10.1016/S2215-0366(14)00007-8.

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Reiman, A. (2018). In consideration of cannabis. *Drug and Alcohol Review*. DOI: 10.1111/dar.12685.

Andinoff, B, and **Reiman, A.** (2019). Implementing social justice in the transition from illicit to legal cannabis. *The American Journal of Drug and Alcohol Abuse*, DOI: 10.1080/00952990.2019.1674862

Reiman, A., Meisel, J., Capler, R. and McCready, D. (2023). Medical cannabis identity and public health paternalism. *Public Health in Practice*, 5. DOI:10.1016/j.puhip.2023.100372.

BOOKS

Reiman, A. (2007). *Medical Cannabis Facilities: Inside cannabis care*. VDM Publishing: Germany.

Reiman, A. (2014). Cannabis Distribution: Coffee Shops to Dispensaries. In *The Cannabis Handbook*. Pertwee, R. (Ed). Pages 339-355.

Reiman (2015). Marijuana as a substitute. In *The American Drug Scene*. Inciardi, J. and McElrath, K. (Eds). Oxford Publishing.

Reiman, A. (2018). Cannabis Legalization in California: A long and winding road. In *Where There's Smoke, There's Fire: The environmental science, public policy and politics of marijuana*. Char Miller (Ed). University Press of Kansas.

Reiman, A. (2022). "The Intersection of Cannabis Reform and Other Progressive Movements: Opportunities for Interdisciplinary Researchers." Chapter 30 in *The Routledge Handbook of Post-Prohibition Cannabis Research: Multidisciplinary Perspectives*, edited by Dominic Corva and Joshua Meisel. New York, NY: Routledge.



Khurshid Khoja
Principal

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500 Capitol Mall
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September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, VA 22152
nprm@dea.gov

Subject: Notice of Appearance by BayMedica, LLC (Docket No. DEA-1362)

Dear Administrator:

Please take notice that my client BayMedica, LLC, a Delaware limited liability company ("BayMedica") will appear in the matter of the Drug Enforcement Administration's Proposed Rule on the Rescheduling of Marijuana, Docket No. DEA-1362 (the "Proposed Rule") and intends to participate in the December 2, 2024 hearing. This notice of appearance ("Notice") is intended to satisfy the requirements of 21 CFR § 1308.44 and 21 CFR § 1316.48; as such, Section (A) of this Notice "state[s] with particularity" BayMedica's "interest ... in the proceeding," Section (B) "state[s] with particularity the objections or issues ... concerning which [it] desires to be heard," and Section (C) briefly states BayMedica's "position ... with regard to the particular objections or issues," and includes descriptions of relevant evidence on material issues of fact and expert opinion that BayMedica intends to present during the hearing per 21 CFR § 1308.42.

(A) BayMedica's Interest in the Proceeding

BayMedica is an "interested person" as defined in 21 CFR 1300.01(b), as it would be "adversely affected or aggrieved by" the Proposed Rule. BayMedica is in the business of meeting consumer demand for certain naturally-occurring, non-intoxicating and currently unscheduled rare and minor cannabinoids (sought after for potential wellness benefits). It does so by supplying cost-effective bioidentical synthetic equivalents of these non-intoxicating cannabinoids through its proprietary production methods and its distribution to lawful manufacturers of hemp and marijuana products ("Non-Intoxicating Cannabinoids").¹ For the fiscal year that ended June 30, 2024, BayMedica's business earned approximately \$4.6 million.²

BayMedica easily satisfies the requirements for being "adversely affected or aggrieved by" the Proposed Rule because the revised definition of "Tetrahydrocannabinol" under 21 CFR § 1308.11 contained within the Proposed Rule (the "Proposed Definition") could make some or all of their business federally illegal.³ As discussed throughout this Notice, BayMedica can credibly allege that it would suffer substantial economic injury if the Proposed Definition were to become final as currently drafted,⁴ and that "that interpretations of the [Proposed



BayMedica's Notice of Intent to Participate in
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Definition's] provisions or scope could directly affect them."⁵ To the extent the Proposed Definition could also contravene the scheduling procedures set forth in Controlled Substances Act ("CSA") at 21 USC §811(a) and 21 USC §811(e), BayMedica also has standing under Section 10(a) of the federal Administrative Procedure Act.⁶

(B) BayMedica Desires to be Heard on the DEA's New Definition for "Tetrahydrocannabinol" under the Proposed Rule

As explained below, BayMedica desires to be heard on the DEA's proposed definition of "Tetrahydrocannabinol" under 21 CFR § 1308.11 offered in the Proposed Rule:

(30) Tetrahydrocannabinols—7370

(i) Meaning tetrahydrocannabinols, except as in paragraphs (d)(30)(ii) and (iii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extracts of such plant, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.

(ii) Tetrahydrocannabinols do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.

(iii) Tetrahydrocannabinols do not include any substance that falls within the definition of marijuana set forth in 21 U.S.C. 802(16).

BayMedica objects to the adoption of the Proposed Definition, as it could permit the DEA to deem currently unscheduled Non-Intoxicating Cannabinoids to be (as a matter of law) Schedule I *tetrahydrocannabinols* (including, but not limited to, therapeutically beneficial and Non-Intoxicating Cannabinoids such as CBC, THCV and THCA).

(1) The DEA's Revisions in the Proposed Definition Create Ambiguity

The Proposed Definition creates unnecessary ambiguity and confusion as drafted, and it could potentially cause currently unscheduled Non-Intoxicating Cannabinoids to be designated as prohibited Schedule I controlled substances without any formal scheduling action or order as required under the CSA at 21 USC §811(a) and 21 USC §811(e) respectively. To convey the full extent of this issue, it's useful to isolate the DEA's proposed revisions to the current existing definition of Tetrahydrocannabinols:



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~~(3130)~~ Tetrahydrocannabinols

(i) Meaning tetrahydrocannabinols, except as in ~~paragraph~~ paragraphs (d)(~~3130~~)(ii) and (iii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous ~~extractives~~ extracts of such plant, ~~and/or~~ synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, ~~such as the following:-~~

~~1-cis or trans-tetrahydrocannabinol, and their optical isomers~~

~~6-cis or trans-tetrahydrocannabinol, and their optical isomers~~

~~3, 4-cis or trans-tetrahydrocannabinol, and its optical isomers~~

~~(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)~~

(ii) Tetrahydrocannabinols ~~does~~ do not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.

(iii) Tetrahydrocannabinols do not include any substance that falls within the definition of marijuana set forth in 21 U.S.C. 802(16).

Note that the carve-out for marijuana-derived THC included under new clause (iii) effectively eliminates the inclusion of any plant derived THC from the Proposed Definition when it is incorporated within clause (i) to modify “tetrahydrocannabinols ... naturally contained in a plant of the genus Cannabis (cannabis plant).” While this was intended to distinguish plant-derived THC from the synthetic forms of THC still classified under Schedule I, it also results in an unnecessarily confusing definition which leaves the reader wondering why the reference to plant-derived THC remains in clause (i).

Additionally, given that hundreds of new pharmacologically active “substances” have been discovered in the cannabis plant since the bulk of the current definition of THC was crafted in 1968 (when it was broadly assumed to be the only active substance in cannabis),⁷ it adds to the confusion of determining the full scope of what’s meant today by the phrase, “synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extracts of such plant” or “synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to *those substances contained in the plant.*”



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It's also worth noting that while the phrase "*with similar chemical structure and pharmacological activity*" was in the DEA's original definition, that standard for inclusion of a synthetic cannabinoid under the rubric of tetrahydrocannabinol is seemingly *less strict* than what would be deemed a Schedule I "analogue" of THC, which require a "substantially similar" chemical structure or pharmacological effect to THC.⁸ This could lead to the inclusion of Non-Intoxicating Cannabinoids like THCV under the Proposed Definition, even though they may exhibit much less similarity to THC than other non-bioidentical synthetic cannabinoids recently scheduled by the DEA.⁹

Finally, the DEA's deletion of the 3 specific examples of THC isomers that constitutes a "tetrahydrocannabinol" also adds to the confusion and ambiguity of determining which cannabinoids fall under the Proposed Definition.

(2) DEA Pronouncements on other Non-Intoxicating Cannabinoids Add to the Confusion

BayMedica's concern is prompted not only by the DEA's construction of and revisions to the Proposed Definition, but also by the DEA's recent pronouncements on THCA. Taken at face value, these pronouncements suggest that the DEA may well apply the Proposed Definition to capture currently lawful Non-Intoxicating Cannabinoids, notwithstanding its longstanding practice (of formally scheduling (1) THC analogues under the Federal Analogues Act (2) synthetic cannabinoids with pharmacological effects that mimic THC under Section 811(a) of the CSA and (3) immediate precursors of other controlled substances under Section 811(a) of the CSA¹⁰) and the absence of any formal scheduling action with respect to those Non-Intoxicating Cannabinoids.

For example, in a recent letter from Terry Boos, Chief of the Drug & Chemical Evaluation Section of Diversion Control Division of the DEA, dated May 13, 2024,¹¹ Dr. Boos communicated the DEA's statutory interpretation of both 21 U.S.C. § 812, Schedule I(c)(17) of the CSA and Section 7 U.S.C. 1639o of the Agriculture Improvement Act of 2018, Public Law 115–334 (the "2018 Farm Bill"), concluding that "*cannabis-derived THCA does not meet the definition of [federally legal] hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9-THC,*" and "[t]he CSA classifies tetrahydrocannabinols (*such as THCA*) as controlled in schedule I" (emphasis added).

While it is absolutely true that THCA has the potential to convert to THC, this was already contemplated by Congress in its approach to defining "hemp". Just as the DEA and federal courts acknowledge that Congress did not intend the threshold defined for Delta-9 THC



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to apply to Delta-8 THC, Congress could not have intended for any guidelines adopted by the USDA to approximate the total potential Delta-9 THC content of pre-harvested hemp¹² to also be a proxy for newly designating THCA as a Schedule I controlled substance equivalent to THC.¹³ Congress was abundantly clear when it defined federally lawful hemp to include

"all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

As such, it serves no purpose for the DEA to attempt to classify THCA as "equivalent to THC" in contravention of Congress' intent in both the CSA and 2018 Farm Bill. As a matter of black letter law THCA is currently *not* a scheduled controlled substance unless it's specifically marijuana-derived. THCA ($C_{22}H_{30}O_4$) has a different chemical structure and molecular formula from THC ($C_{21}H_{30}O_2$), is *not* a "derivative" or "isomer" of THC (nor is it an analogue) and as a Non-Intoxicating Cannabinoid it does *not* display the same pharmacological activity as THC. Thus, as a different cannabinoid from THC, THCA would need to be scheduled before it could be legally deemed the functional equivalent of a Schedule I controlled substance. However, THCA has never been through formal scheduling by the DEA, as an examination of the Federal Register proves.¹⁴

Even as an immediate precursor of THC (per 21 USC §802(23)), THCA still can't be deemed a Schedule I-equivalent based solely on the DEA's pronouncements in response to individual *ex parte* correspondence (creating an "underground regulation"). At a minimum, the DEA would need to first issue a formal order and publish it to the Federal Register (per 21 USC §811(e) and 21 CFR §1308.47).

(C) Given the foregoing issues with the Proposed Definition, BayMedica is deeply concerned that the DEA will attempt to surreptitiously schedule other Non-Intoxicating Cannabinoids as Schedule I Tetrahydrocannabinols, Depriving BayMedica of Due Process Rights, and Potentially Rendering Some or All of its Business Federally Unlawful

BayMedica is deeply concerned that the DEA will attempt similar end runs around the CSA to surreptitiously schedule other Non-Intoxicating Cannabinoids as Schedule I Tetrahydrocannabinol. As with its attempts to schedule THCA on the fly, this would be contrary to Congress' intent in establishing procedures under the CSA for the scheduling the immediate precursors of scheduled controlled substance, its intent in defining controlled substance analogues under the Federal Analogue Act, its intent in specifically scheduling THC for its



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intoxicating pharmacological properties, and settled law per valid federal Circuit Court precedents.

Federal appellate precedents established prior to the 2018 Farm Bill are instructive on this point as they have addressed previous attempts by the DEA to expand the definition of "tetrahydrocannabinol," and are still valid law¹⁵ notwithstanding the passage of the 2018 Farm Bill. In *Hemp Indus. Ass'n v. DEA*,¹⁶ a trade association representing numerous manufacturers and importers of non-psychoactive hemp foodstuffs challenged DEA Final Rules which sought to expand the definition of "Tetrahydrocannabinols" to include any naturally occurring THC regardless of whether such THC is derived from marihuana or hemp (which was more narrowly defined at the time to exclude the flowering tops and resin derived therefrom, but still federally lawful if cultivated outside the United States) and would have effectively prohibited the theretofore lawful importation and sale of such non-psychoactive hemp foodstuffs with even trace amounts of THC.¹⁷ In its ruling in *Hemp Indus. Ass'n v. DEA*, the Ninth Circuit permanently enjoined the DEA from enforcing the CSA against manufacturers and importers of such products through the DEA's expanded definition for Tetrahydrocannabinols.

The *HIA* court held that the DEA could not prohibit trace amounts of hemp-derived THC on the basis that THC (which at the time was specifically defined by DEA regulations as being synthetically-derived) and marijuana (containing naturally-occurring THC) were both deemed Schedule I controlled substances, and would first need to formally schedule hemp-derived THC before it could prohibit the importation of hemp foods due to trace amounts of THC. In its holding, the Ninth Circuit stated that while the DEA could "regulate foodstuffs containing natural THC if it is contained within marijuana, *and* can regulate synthetic THC of any kind ... they *cannot regulate naturally-occurring THC not contained within or derived from marijuana—i.e., non-psychoactive hemp products—because non-psychoactive hemp is not included in Schedule I,*" concluding in no uncertain terms that "*[t]he DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance.*"¹⁸

Should BayMedica be permitted to appear at the hearing, we intend to submit Exhibit A to this Notice into the record as evidence of a material issue of fact, as well as the various sources cited in the endnotes to this Notice. Additionally, Shane Johnson, MD, BayMedica's Senior Vice President & General Manager, is willing to present his expert opinion at the hearing in support of BayMedica's position. Shane holds a Bachelor of Science in Neuroscience from Brown University, and a Medical Degree from Stanford University. He is a founder of BayMedica and is well versed in the utility of cannabinoids in the health and wellness sector, as well as the various approaches to producing nature-identical cannabinoids including extraction,



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semi-synthesis from hemp derived starting materials, and full synthesis using both chemistry and/or biosynthesis.

Please send all notices regarding this Notice of Appearance to the following addressees:

Khurshid Khoja, Esq.
CEO & Principal Attorney
c/o Greenbridge Corporate Counsel, P.C.
500 Capitol Mall, Suite 2350
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Shane Johnson, MD
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BayMedica, LLC
930 Tahoe Blvd., Ste. 802-433
Incline Village, NV 89451
sjohnson@baymedica.com

Respectfully yours,

A handwritten signature in blue ink, appearing to read "Khurshid Khoja".

Khurshid Khoja, Esq.

cc: Shane Johnson, MD

¹ Though BayMedica is also a member of the National Cannabis Industry Association ("NCIA"), the views presented herein are BayMedica's, and should not be attributed to NCIA. That said, there are no doubt other persons in the cannabis industry that are similarly situated to BayMedica and would also be adversely affected by the Proposed Rule.

² See "InMed Pharmaceuticals Reports Full Year Fiscal 2024 Financial Results and Provides Business Update," *Yahoo Finance*, Sept. 30, 2024: (<https://finance.yahoo.com/news/inmed-pharmaceuticals-reports-full-fiscal-120000533.html>).

³ Note that BayMedica can show that they are "person adversely affected or aggrieved by" the Proposed Rule (as this phrase is employed in the definition of "interested person" under 21 CFR 1300.01(b)) by showing that they meet the standard set in section 10(a) of the Administrative Procedure Act for being "adversely affected or aggrieved by" an agency action, *notwithstanding* the fact that they are not invoking standing to seek judicial review of a final agency rule. In other words, if BayMedica can demonstrate that they would be "adversely affected or aggrieved by" if the Proposed Definition were codified in a final DEA rule, they can demonstrate the same with respect to the Proposed Rule as well. See *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1200 (9th Cir. 2004). In *Sausalito* the court instructs that "if statutory standing is not explicitly provided in the text of a statute," or in our case 21 CFR 1300.01(b), "a [party] challenging federal administrative action looks to Section 10(a) of the Administrative Procedure Act (APA), which provides that any 'person ... adversely affected or aggrieved by agency



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action within the meaning of a relevant statute, is entitled to judicial review thereof.' 5 U.S.C. § 702." *Id.* Additionally, under 21 CFR 1300.01(b)), a "person" is not limited to individuals and includes "any ... corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."

⁴ See *Idaho ex rel. Kempthorne v. U.S. Forest Serv.*, 142 F. Supp. 2d 1248, 1255 (D. Idaho 2001): "Section 10(a) of the APA provides that 'a person ... adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.' 5 U.S.C. § 702. In cases arising under the APA, the standing requirement has been read to mean that plaintiffs must show 'the challenged action ha[s] caused them injury in fact' and that the injury is 'to an interest arguably within the zone of interests to be protected or regulated by the statutes that the agencies were claimed to have violated.' *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1514 n. 12 (9th Cir.1992)."

⁵ See *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1200 (9th Cir. 2004):

Interpreting the APA, the Supreme Court in *Association of Data Processing Service Organizations v. Camp*, 397 U.S. 150, 153, 90 S.Ct. 827, 25 L.Ed.2d 184 (1970), held that anyone "arguably within the zone of interests" protected by the statute under which he or she has asserted injury has standing to bring suit under that statute. The Court has instructed that the "zone of interests" test is to be construed generously, stating that the "test is not meant to be especially demanding," and that a court should deny standing under the "zone of interest" test only "if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Clarke v. Secs. Indus. Ass'n*, 479 U.S. 388, 399, 107 S.Ct. 750, 93 L.Ed.2d 757 (1987); see also *Thinket Ink Info. Res., Inc. v. Sun Microsystems, Inc.*, 368 F.3d 1053, 1059 (9th Cir.2004); *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1120–21 (9th Cir.2004). Specifically, "there need be no indication of congressional purpose to benefit the would-be plaintiff." *Graham v. Fed. Emergency Mgmt. Agency*, 149 F.3d 997, 1004 (9th Cir.1998) (citing *Clarke*, 479 U.S. at 399–400, 107 S.Ct. 750).... To determine whether [a party] is within the zone of interests of the statutes under which it brings suit, we look "to the substantive provisions of the [statutes], the alleged violations of which serve as the gravamen of the complaint." *Bennett v. Spear*, 520 U.S. 154, 175, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997). We are instructed by *Clarke* to understand these substantive provisions liberally. Thus, "APA plaintiffs need only show that their interests fall within the 'general policy' of the underlying statute, such that interpretations of the statute's provisions or scope could directly affect them." *Graham*, 149 F.3d at 1004 (quoting *Nat'l Credit Union Admin. v. First Nat'l Bank and Trust Co.*, 522 U.S. 479, 487–88, 118 S.Ct. 927, 140 L.Ed.2d 1 (1998) (further citations omitted)).

⁶ See 5 U.S.C. § 702.

⁷ See DEA's Rule *Interpretation of Listing of "Tetrahydrocannabinols" in Schedule I* (10/09/2001), Docket No. DEA-204, 66 FR 51530 <https://www.federalregister.gov/d/01-25022/p-40> .

⁸ See 21 U.S.C. §802(32)(A):



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(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance-

(i) the chemical structure of which is *substantially similar* to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is *substantially similar* to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include-

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

⁹ See DEA Proposed Rule Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in Schedule I, (03/30/2021), Docket No. DEA-491, 86 FR 16553, <https://www.federalregister.gov/documents/2021/03/30/2021-06553/schedules-of-controlled-substances-placement-of-5f-edmb-pinaca-5f-mdmb-pica-fub-akb48#p-31> .

¹⁰ See DEA's Proposed Rule Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, Docket No. DEA-496, 84 FR 48815.

¹¹ See Exhibit A to BayMedica Notice of Appearance (May 13, 2024 Letter from Dr. Terry Boos).



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¹² See the USDA's *Laboratory Testing Guidelines U.S. Domestic Hemp Production Program* available at <https://www.ams.usda.gov/rules-regulations/hemp/information-laboratories/lab-testing-guidelines>

¹³ See *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682 (9th Cir. 2022); see also Letter from Terrence L. Boos, Chief, Drug & Chem. Evaluation Section, Diversion Control Div., U.S. Dep't of Just. Drug Enf't Admin., to Donna C. Yeatman, Exec. Sec'y, Ala. Bd. of Pharmacy (Sept. 15, 2021), <https://hempindustrydaily.com/wp-content/uploads/2021/11/DEA-letter-to-AL-BOP.pdf>.

¹⁴ See <https://www.federalregister.gov/documents/search?conditions%5Bagencies%5D%5B%5D=drug-enforcement-administration&conditions%5Bterm%5D=Tetrahydrocannabinolic+Acid>

¹⁵ The holding *Hemp Indus. Ass'n v. DEA* is still the current law, as the DEA did not appeal the Ninth Circuit's decision to the U.S. Supreme Court.

¹⁶ *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012 (9th Cir. 2004).

¹⁷ See the DEA's Rule re *Clarification of Listing of "Tetrahydrocannabinols" in Schedule I*, DEA 205-F (published March 21, 2003), 68 Fed. Reg. 14114, and its Rule re *Exemption From Control of Certain Industrial Products and Materials Derived From the Cannabis Plant*, DEA 206-F (published March 21, 2003), 68 Fed. Reg. 14119.

¹⁸ *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1018 (9th Cir. 2004) (emphasis added).

EXHIBIT A to Notice of Appearance by BayMedica, LLC (Docket No. DEA-1362)



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

www.dea.gov

May 13, 2024

Mr. Shane Pennington
Porter Wright Morris & Arthur LLP
2020 L Street, NW Suite 600
Washington, D.C. 20006

Dear Mr. Pennington:

This is in response to your letter dated April 25, 2024, in which you requested the control status of tetrahydrocannabinolic acid (THCA) under the Controlled Substances Act (CSA). For THCA, we are assuming THCA is referencing delta-9-THCA. The Drug Enforcement Administration (DEA) conducted a review of the CSA and its implementing regulations with regard to these questions.

The CSA classifies tetrahydrocannabinols (such as THCA) as controlled in schedule I. 21 U.S.C. § 812, Schedule I(c)(17); 21 CFR 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term “tetrahydrocannabinols” means those “naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.” 21 CFR § 1308.11(d)(31). Thus, tetrahydrocannabinols synthetically produced from non-cannabis materials is controlled under the CSA as a “tetrahydrocannabinol.”

The CSA, however, excludes “hemp” from the definition of marihuana and the classification of tetrahydrocannabinols in Schedule I. 21 U.S.C. 802(16)(B)(i); 21 U.S.C. 812, Schedule I(c)(17). The term “hemp” is “the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. § 1639o.

Accordingly, naturally occurring tetrahydrocannabinols extracted from the cannabis plant that have a delta-9-tetrahydrocannabinol (delta-9-THC) concentration of not more than 0.3 percent on a dry weight basis meet the definition of “hemp” and thus are not controlled under the CSA. Conversely, a naturally derived cannabinoid having a delta-9-THC concentration more than 0.3 percent on a dry weight basis is controlled in schedule I under the CSA as marihuana.

In regards to THCA, Congress has directed that, when determining whether a substance constitutes hemp, the delta-9-THC concentration is to be tested “using post-decarboxylation or other similarly reliable methods.” 7 U.S.C. § 1639p(a)(2)(A)(ii); 7 U.S.C. § 1639q(a)(2)(B). The “decarboxylation” process converts delta-9-THCA to delta-9-THC. Thus, for the purposes of

Mr. Shane Pennington

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enforcing the hemp definition, the delta-9-THC level must account for any delta-9-THCA in a substance. Accordingly, cannabis-derived THCA does not meet the definition of hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9-THC.

If you have any further questions, please contact the Drug and Chemical Evaluation Section at DPE@dea.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Boos".

Terrence L. Boos, Ph.D., Chief
Drug & Chemical Evaluation Section
Diversion Control Division

Cc: Washington Division Office



Drug Enforcement Administration,
Attn: Administrator Hon. Anne Milgram
Docket No. DEA-1362
8701 Morrisette Drive,
Springfield, Virginia 22152

RE: Notice of Intention to Participate in Hearing on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram:

Last Prisoner Project (“LPP”) hereby files this notice of our intention to participate in the hearing scheduled for December 2, 2024, at 9 a.m. ET on the Proposed Rule that would reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act (“CSA”).¹

I. Introduction

LPP is a 501(c)(3) non-profit organization that advocates on behalf of individuals sentenced for nonviolent marijuana offenses, as well as for those still suffering the collateral consequences of a marijuana offense on their criminal record. LPP supports the rescheduling of marijuana from Schedule I, but urges the Drug Enforcement Administration (“DEA”) to remove marijuana from the CSA entirely given its medical benefits, low potential for abuse, and the adverse outcomes on communities, particularly communities of color, who have faced disproportionate criminalization as a result of marijuana’s current scheduling. We agree with the Department of Health and Human Services (“HHS”) finding that marijuana has a currently accepted medical use in the United States and a low potential for abuse. What is absent from HHS’s recommendation, however, is a consideration of the harms to communities and negative

¹ See 89 Fed. Reg. 44,597 (May 21, 2024), Docket No. DEA-1362 (“NPRM”).

public health outcomes of keeping marijuana classified as a Schedule I substance. We request the opportunity to testify at the public hearing as to the negative public health outcomes of the continued criminalization of marijuana, as well as the unfair restrictions on accessing medicinal marijuana for individuals impacted by the criminal legal system.

II. The interests of the person in the proceeding

As an organization, LPP represents individuals who suffer dire consequences as a result of marijuana's current status as a Schedule I substance. Our organization is comprised of individuals who have been incarcerated for cannabis offenses or suffered adverse outcomes as a result of a cannabis conviction, attorneys, drug policy experts, and advocates for both criminal legal reform and just drug policy that balances the needs of public safety with public interest.

The overcriminalization of communities for marijuana-related activities is not only unjust, but it creates an unnecessary burden on our public safety apparatus, our economy, and has a substantial impact on public health. Indeed, the criminalization of marijuana itself poses health risks particularly for already vulnerable populations. Further, keeping marijuana in Schedule I also reduces access for LPP's constituency of much-needed medicine. Particularly for those who have been impacted by the criminal legal system, and may still be under some form of community supervision, keeping marijuana federally illegal poses significant risks to those who may benefit from its use.

LPP and its constituents would be adversely affected by the proposed rule and our interests differ from other potential participants. Given the makeup of our organization and the particularized interests we represent, we are best suited to provide evidence and testimony specific to those interests that would not otherwise be represented. Our interest in this proceeding is analogous to the interests of other public interest and advocacy organizations whose requests for a hearing on the record during past attempts to reschedule marijuana were granted.²

III. The objections or issues concerning which the person desires to be heard

The adverse outcomes on marginalized communities resulting from marijuana's current status as a Schedule I substance

For decades, marijuana-related criminalization and incarceration have posed significant long-term health risks, particularly in communities of color. In 2013, a report from the American Civil Liberties Union ("ACLU") found that, despite virtually indistinguishable rates of marijuana consumption amongst racial groups, Black residents of the United States were 3.73 times more likely to be arrested for marijuana possession than their white counterparts.³ A 2020 follow-up to the ACLU report found that, despite several states legalizing or decriminalizing marijuana, these racial disparities remained essentially

² See, e.g., *NORML v. DEA*, 559 F.2d 735, 742 (D.C. Cir. 1977) (noting that "NORML and the American Public Health Association" successfully requested a hearing on rescheduling marijuana).

³ American Civil Liberties Union Report, *The War on Marijuana in Black and White: Billions of Dollars Wasted on Racially Biased Arrests*, 2013, <https://www.aclu.org/wp-content/uploads/legal-documents/1114413-mj-report-rfs-re11.pdf>.

unchanged.⁴ Data indicates that these racial disparities appear to persist in conviction rates and sentencing.⁵ These health implications are most evident when investigating discrepancies in life expectancy, rates of illness and hospitalizations, and mental health disturbances.

The research surrounding the relationship between incarceration and diminished life expectancies is unequivocal. Studies have shown that “each year in prison takes 2 years off an individual’s life expectancy.” And more broadly, “mass incarceration has shortened the overall US life expectancy by 5 years.”⁶ Even upon release, these impacts continue, given that mortality rates for individuals under any form of community supervision are two to three times higher than the general population.⁷ It is also worth noting that many incarcerated individuals already face increased health risks due to disproportionate methods of policing. This is further compounded by the overcriminalization of marijuana, especially in communities of color, which for various reasons, already face diminished life expectancies. Furthermore, data shows that “people aged 55 years and older are among the fastest growing segments of the incarcerated population. Older adults have higher rates of chronic conditions and mental and physical disabilities.”⁸

While incarcerated, individuals are often subject to unsanitary conditions, environmental hazards, physically uninhabitable living quarters, and lack basic medical access, nutritional sustenance, and mental health resources.⁹ The impacts of these factors are clear in the relationship between incarceration and rates of illnesses and hospitalizations. Research shows that individuals who are incarcerated are more likely “to have high blood pressure, asthma, cancer, arthritis, and infectious diseases, such as tuberculosis, hepatitis C.”¹⁰ HIV/AIDS is two to seven times more prevalent amongst incarcerated populations, and an estimated 17% “of all people with HIV living in the U.S. pass through a correctional facility each year.”¹¹

⁴ American Civil Liberties Union Report, *A Tale of Two Countries: Racially Targeted Assets in the Era of Marijuana Reform*, Apr. 16, 2020,

<https://www.aclu.org/report/tale-two-countries-racially-targeted-arrests-era-marijuana-reform>.

⁵ A 2021 analysis of federal prison population estimated that 60% of approximately 3,016 individuals serving time in federal prison for marijuana offenses were of Hispanic descent, and over the past five years, 67% of individuals receiving prison sentences for marijuana offenses were Hispanic. Recidiviz Report, *Ending Federal Prison Sentences for Marijuana Offenses* (2021),

https://assets.website-files.com/5e7ff048d75a9b3c5df52463/61abf4d36aefde8dec64a000_FED_SRA_final_12.2.21.pdf.

⁶ Emily Widra, *Incarceration shortens life expectancy*, June 26, 2017,

https://www.prisonpolicy.org/blog/2017/06/26/life_expectancy/

⁷ Alexi Jones and Emily Widra, *Mortality, health, and poverty: the unmet needs of people on probation and parole*, Apr. 3, 2023, https://www.prisonpolicy.org/blog/2023/04/03/nsduh_probation_parole/

⁸ Vera Institute, *On Life Support: Public Health in the Age of Incarceration*, Nov. 2014,

<https://www.vera.org/downloads/publications/on-life-support-public-health-mass-incarceration-overview.pdf>

⁹ Leah Wang, *Prisons are a daily environmental injustice*, Apr. 20, 2022,

https://www.prisonpolicy.org/blog/2022/04/20/environmental_injustice/

¹⁰ Healthy People 2030, *Incarceration*,

<https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/incarceration#:~:text=Studies%20have%20shown%20that%20when.%2C%20hepatitis%20C%2C%20and%20HIV.>

¹¹ Vera Institute, *On Life Support: Public Health in the Age of Mass Incarceration*, November 2014,

<https://www.vera.org/downloads/publications/on-life-support-public-health-mass-incarceration-overview.pdf>

Similarly, “hepatitis C occurs at rates 8 to 21 times higher among incarcerated people.”¹² Overall, rates of hospitalization are significantly higher in individuals who have been incarcerated than they are in the general population.¹³ Additionally, due to the lingering collateral consequences attached to a criminal conviction, individuals are at a much higher risk of entering states of risk and poverty upon release, leaving many of these health concerns to exacerbate.

Individuals who are incarcerated or under community supervision are significantly more likely to experience mental health and substance abuse problems throughout their lifetime.¹⁴ Research shows that the prevalence of serious mental illness is two to four times higher in jails and prisons.¹⁵

The consequences of these health risks ripple beyond prison doors. Not only do individuals continue to face significant health risks upon release due to their long-term nature, , the risks also permeate throughout entire communities. A recent study demonstrated that children who have had a family member incarcerated experience poorer health outcomes later in life. So much so that individuals who have a family member who is currently or formerly incarcerated have a shorter life expectancy by 2.6 years.¹⁶ With these health crises in mind, LPP believes that the mere rescheduling of marijuana—which allows the continued criminalization of marijuana use and imprisonment for marijuana offenses —perpetuates the public health risks associated with incarceration. Therefore, we urge the DEA to go further, and to decontrol marijuana, thus reducing criminal penalties and creating avenues for individuals currently serving time for marijuana offenses to seek relief. We believe that this would significantly improve the nation's public health in numerous ways. Not only would it improve the health crisis within prisons by mitigating overcrowding, but it would also improve the health outcomes of individuals incarcerated for marijuana offenses by shielding them from the hazardous conditions of prisons, ultimately uplifting surrounding communities as well.

Lastly, completely eliminating criminal penalties for marijuana and ending lengthy sentencing practices for marijuana-related offenses also enables scarce public health and safety resources to be focused where they are most needed. Removing marijuana from the CSA entirely not only comports with legalization trends in half of the states, but also with the sentiment that a vast majority of Americans believe marijuana should be legalized. These shifting sentiments are made clear by the significant decrease in federal prosecutions for simple marijuana possession, which have been declining steadily from 2,172 in fiscal year 2014 to only 145 in fiscal year 2021.¹⁷ As of January 2022, no offenders sentenced solely for simple

¹² *Id.*

¹³ AAFP, *Incarceration and Health: A Family Medicine Perspective (Position Paper)*, <https://www.aafp.org/about/policies/all/incarceration.html>

¹⁴ Prison Policy Institute, *Public Health*, <https://www.prisonpolicy.org/health.html>

¹⁵ Vera Institute, *On Life Support: Public Health in the Age of Mass Incarceration*, November 2014,

<https://www.vera.org/downloads/publications/on-life-support-public-health-mass-incarceration-overview.pdf>

¹⁶ Emily Widra, *New data: People with incarcerated loved ones have shorter life expectancies and poorer health*, July 12, 2021, <https://www.prisonpolicy.org/blog/2021/07/12/family-incarceration/>

¹⁷ United States Sentencing Commission, *Weighing the Impact of Simple Possession of Marijuana Trends and Sentencing in the Federal System*, January 2023,

possession of marijuana remained in the custody of the Federal Bureau of Prisons.¹⁸ This demonstrates the shift in American sentiment given the growing body of research and evidence suggesting the safety of marijuana and its potential medical benefits, as has been indicated by numerous other commenters. Given this, continuing to invest in marijuana-related incarceration not only goes against the current national sentiment, it also pilfers money away from public health and safety resources.

Lack of access for individuals impacted by the criminal legal system

The medicinal benefits of marijuana are well known and well documented, and HHS has included potential uses for medical marijuana in their recommendation. Currently, the conflict between state and federal law makes accessing this potentially life-saving medicine difficult for the vast majority of the public, and especially for our constituency which we wish to advocate for in this hearing. While a move to Schedule III would improve access for some patients, it is likely to continue to hinder those impacted by a criminal conviction from accessing the potential medicinal benefits of marijuana. Simply because an individual has a criminal conviction on their record or is under community supervision does not mean that they should be denied access to needed medicine.

One such individual is LPP constituent Michael Pelletier. In 2006, Michael Pelletier was convicted of importing marijuana from Canada and sentenced to life imprisonment without the possibility of parole. Michael, who has been confined to a wheelchair since enduring a farm injury when he was 14-years-old, had been using marijuana to treat his pain. On January 20, 2021, Michael was granted a presidential commutation.¹⁹ Today, Michael would greatly benefit from using medical marijuana for chronic pain caused by his condition. Due to marijuana's status as a Schedule I substance, however, he cannot access this medicine without fear of violating the terms of his probation. Michael's life and health outcomes have already been greatly diminished due to the criminalization of marijuana. As someone who has served his sentence and shown that he is rehabilitated, he deserves to live life to the fullest and not continue to suffer devastating pain because of the illegality of marijuana and his status as an impacted individual.

Fully removing marijuana from the controlled substances list would greatly improve access for impacted individuals who would otherwise be at risk of further criminal or technical violations of the terms of their supervised release. At a hearing, we would provide evidence on this as well as constituent testimony regarding the lack of access for impacted individuals. We would also provide further evidence on the public health concerns of the criminalization of marijuana, as well as the myriad potential medicinal benefits of marijuana to our constituency. We greatly appreciate the opportunity to participate in this important hearing on the Proposed Rule.

https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2023/20230509_Marijuana-Possession.pdf

¹⁸ *Id.*

¹⁹President Trump, The White House, *Statement from the Press Secretary Regarding Executive Grants of Clemency*, Issued on: January 20, 2021

<https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-regarding-executive-grants-clemency-012021/>

All notices to be sent pursuant to the proceeding should be addressed to:

Sarah Gersten
149 Walden St
West Hartford, CT 06107
sarah@lastprisonerproject.org

Respectfully submitted,



Sarah Gersten
Executive Director and General Counsel
Last Prisoner Project

1312 17th STREET SUITE 640 DENVER, CO 80202

WWW.LASTPRISONERPROJECT.ORG

September 30, 2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Attn: Administrator, 8701 Morrisette Drive

Springfield, VA 22152

Subject: Notice of Appearance

Dear Madam/Sir:

Please take notice that Michael Doyle will appear in the matter of: Docket No. DEA-1362

I, Michael Doyle, hereby attest and proclaim a particular interest as a person in recovery from substance use and alcohol disorder, in the matter of the re-scheduling of Marijuana.

I, Michael Doyle, hereby swear and affirm that I consider the current scheduling to be an undue burden upon myself and millions of others in recovery.

I, Michael Doyle, affirm and hold true, that the undue burden of classifying a naturally occurring plant in the current DEA scheduling system has caused harm and continues to cause harm to many people who may want to use naturally occurring harm reduction options, as opposed to lesser classified drugs in schedule IV (In particular Benzodiazepines) to help in the ease and comfort in recovery. As a subject matter expert and person with lived experience, who has not engaged in alcohol use or illicit manufactured chemical drug use, since October 20, 2013.

All notices to be sent pursuant to this appearance should be addressed to:

Michael Doyle

12619 Dunks Ferry Rd.

Philadelphia, PA 19154

Respectfully yours,

DocuSigned by:

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9/30/2024 | 11:51 PM EDT

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Subject: Here is your signed document: Docket No. DEA-1362.pdf

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Time Zone: (UTC-05:00) Eastern Time (US & Canada)

mike@themikedoylegroup.com

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mike@themikedoylegroup.com

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MichaelDoyle

mike@themikedoylegroup.com

EXP Realty LLC

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Pat Barth

michaeldoylejr@comcast.net

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Witness Events**Signature****Timestamp****Notary Events****Signature****Timestamp****Envelope Summary Events****Status****Timestamps**

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9/30/2024 11:51:15 PM

Payment Events**Status****Timestamps**

September 30, 2024

Drug Enforcement Administration, Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ
8701 Morrisette Drive
Springfield, Virginia 22152

Subject: Notice of Appearance (Docket No. DEA-1362)

Dear Administrator Milgram:

Please take notice that Natalie P. Hartenbaum, MD, MPH will appear in the matter of: Schedules of Controlled Substances: Rescheduling of Marijuana (Docket No. DEA-1362) on behalf of the American College of Occupational and Environmental Medicine (ACOEM).

(A) (State with particularity the interest of the person in the proceeding.).

Dr. Natalie Hartenbaum is certified by the American Board of Internal Medicine and the American Board of Preventive Medicine (Occupational Medicine in Occupational and Environmental Medicine). She has been listed on the Federal Motor Carrier Safety Administration's (FMCSA) NRCME since its inception and is a certified Medical Review Officer (MRO). Dr. Hartenbaum has extensive experience in clinical, corporate, and academic settings. She is a nationally recognized expert in workplace drug testing and occupational fitness for duty with a special focus on transportation.

Dr. Hartenbaum has participated in several related projects including serving as Chair of ACOEM's Cannabis in the Workplace Task Force; the National Safety Council's Impairment Advisory Board; FMCSA Medical Expert Panels on Schedule II Medications; National Academy of Science's Panel on Research Methodologies and Statistical Approaches to Understanding Driver Fatigue Factors in Motor Carrier Safety and Driver Health; Medical Standards for Railroad Workers for the Federal Motor Railroad Administration; and Prescription and Over-the-Counter Medication Toolkit for the Federal Transit Administration.

Dr. Hartenbaum is on the teaching faculty at the University of Pennsylvania. She is a Past President of ACOEM and a former member of the Board of Trustees of the American Board of Preventive Medicine.

ACOEM's interest in this matter is to protect the health of American workers and the public by ensuring commercial and public transportation safety. ACOEM is the nation's largest medical society dedicated to promoting worker health through preventive medicine, clinical care, research, and education. The College represents Occupational and Environmental Medicine (OEM) physicians and other healthcare professionals devoted to preventing and managing occupational and environmental injuries and exposures. Many of our member physicians serve as Medical Review Officers (MROs) under the U.S. Department of Transportation's (DOT) drug testing program or Commercial Driver Medical Examiners under the FMCSA's Medical Standards program.

This proposed action would directly impact our members and the workers they serve, as rescheduling would end the DOT's ability to test safety-sensitive transportation employees for marijuana drug testing and effect deterrence for commercial transportation safety-sensitive employees across the nation. Safety-sensitive employees have been subject to testing for marijuana and other drugs since shortly after catastrophic accidents caused by marijuana use occurred in the mid and late 1980s. Rescheduling marijuana to Schedule III would abruptly end DOT-regulated testing for marijuana, which could jeopardize transportation safety in the U.S., potentially endangering American workers and the public.

As mentioned above, our members are on the front lines of protecting the safety of commercial and public transportation nationwide. As physicians, our members have an ethical and professional obligation to care for the health of workers and the public by serving in roles that help maintain effective measures to prevent needless accidents caused by those under the influence of marijuana and other impairing substances.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

ACOEM, via Dr. Hartenbuam, would like to provide expert testimony at the hearing on the serious potential unintended consequences that may impact public health and safety if they are not addressed before any change in marijuana's schedule under the Controlled Substance Act (CSA). This testimony will focus on the eight factors set forth for rescheduling under the CSA in 21 U.S.C. 811(c), emphasizing

factor six (What, if any, risk there is to the public health). Dr. Hartenbaum's testimony will also focus on concerns regarding the unintended consequences of this proposed action on related Federal rules.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

ACOEM is concerned that if the final decision is to move marijuana to Schedule III, there will be significant problems ensuring safety in the workplace (e.g., drug testing safety-sensitive workers). The U.S. Department of Health and Human Services (HHS) does not have the authority to test for Schedule III drugs. The authority of HHS to test for and to certify laboratories for testing is provided by Executive Order 12564– Drug-free Federal Workplace of Sept. 15, 1986 (E.O. 12564). Under E.O. 12564, HHS is only authorized to test for drugs and certify laboratories to test for drugs that are in Schedule I or II for the CSA. Specifically, E.O. 12564, Section 7(c) states: “For purposes of this Order, the term ‘illegal drugs’ means a controlled substance included in Schedule I or II, as defined by section 802(6) of Title 21 of the United States Code.” Sections 3.2 (a) of both the HHS Mandatory Guidelines for Urine and the HHS Mandatory Guidelines for Oral Fluid state that an employee may be tested for “any drugs listed in Schedule I or II of the Controlled Substances Act.”

If marijuana becomes a Schedule III substance, HHS would no longer be able to test for or certify laboratories to test for marijuana. As a result, DOT immediately would no longer be able to test for marijuana because The Omnibus Transportation

Employee Testing Act of 1991 (OTETA) requires the DOT to rely on HHS for the science of drug testing (the drug cutoffs and scientific protocols), as well as conducting all DOT-regulated testing through HHS-certified laboratories.

ACOEM believes that additional research on the safety, efficacy, risks, and benefits of marijuana is needed. This must include how these may differ on many factors, including, but not limited to, the potency (concentration of the active ingredient(s) of the final product), the route of consumption, potential interaction with other medications or treatments, and the appropriate dose and dosing scheduling. It is not currently possible to provide information regarding the duration of impairment and safety incapacitation after use, given the lack of a well-established and agreed-upon threshold of impairment combined with widely varying doses in products, various routes of administration, and in the case of oral use, varying rates of GI absorption. While a better method is needed for drug testing in a deterrence-based program, in those industries where working while under the influence would present a significant public health/safety risk, the current process should be replaced with a better process, not eliminated. There is a need to move forward with identifying and implementing better test modalities to shorten the window of detection for marijuana but retain the ability to test for this substance in federal and private safety sensitive drug testing programs employees.

ACOEM believes it is essential that if marijuana is moved out of Schedule I, employers should be free to enact policies regarding allowing or precluding marijuana/cannabinoids in their workers in any safety sensitive work (including

motor vehicle operation, other modes of transportation, forklift driving, overhead crane operation, heavy equipment operation, work with sharps, work with the risk of injury (e.g., heights) and tasks involving high levels of cognitive function).

While ACOEM recognizes that HHS's scientific and medical determinations are accorded "significant deference" through the rulemaking process, we believe there is a wide range of evidence related to the scientific and medical determinations on the issues at hand, which does not present a clear-cut evidence base to support this proposed action. In ACOEM's view, of the 8-factor analysis used to reschedule a drug, the only one where there is consistent, universally agreed sufficient research is that marijuana is not an immediate precursor of a substance that is already controlled. From ACOEM's perspective, the ability to conduct research into the appropriate placement of marijuana on the CSA and mechanisms to mitigate potential impacts on public safety is essential. Potential barriers to this research must be addressed before this proposed action is finalized, to ensure that there is an acceptable risk to public health and safety.

All notices to be sent pursuant to this appearance should be addressed to:

Natalie P. Hartenbaum, MD, MPH, FACOEM
American College of Occupational and Environmental Medicine (ACOEM)
25 Northwest Point Boulevard, Suite 700
Elk Grove Village, IL 60007-1030
Via email to: occumedix@comcast.net cc: craig@acoem.org

Respectfully yours,





September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

RE: Notice of Intention to Participate in Hearing on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Introduction

Pursuant to 21 U.S.C. 811(a) and 21 CFR 1308.41, the National Cannabis Industry Association (NCIA) formally requests to appear at the December 2, 2024 hearing on the NPRM (Docket No. DEA-1362) regarding the rescheduling of marijuana.

Founded in 2010, NCIA is the largest and longest-running trade association representing the legal cannabis industry. Our organization represents more than 500 state-legal cannabis and cannabis-related businesses across the nation. Our members are primarily small, independent businesses and all are dedicated to replacing the failed policies of marijuana prohibition with sensible regulations that protect public health and foster economic development.

NCIA has standing to participate in a hearing, as our member businesses are regulated by the Proposed Rule and the Controlled Substances Act (CSA). Our organization is prepared and uniquely positioned to present expert testimony on marijuana's currently accepted medical use in treatment in the United States, potential impact on state marijuana programs and regulations, the economic implications of moving marijuana to Schedule III, relevant international treaty obligations, interplay with the Food, Drug, and Cosmetic Act (FD&C Act) and the placement of marijuana (and other cannabinoids) within the CSA. A decision not to reschedule or deschedule marijuana would also adversely affect NCIA and our members with significant tax implications and regulatory uncertainty, which would undoubtedly negatively impact public health and safety, as well as harm tens of thousands of small businesses and hundreds of thousands of cannabis industry employees across the country.

Additional information on NCIA's membership, expertise, and standing to participate in the upcoming hearing can be found in the organization's public comment¹ on the NPRM.

¹ "Request for Public Comment on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362 (A.G. Order No. 5931-2024)." *The National Cannabis Industry Association*, 22 July 2024, thecannabisindustry.org/91-of-rescheduling-public-comments-call-for-reform/. Accessed 30 Sep. 2024.

Currently Accepted Medical Use

Our organization agrees with the Department of Health and Human Services' (HHS) conclusion that marijuana has a potential for abuse less than the other substances in schedules I and II; that marijuana has a currently accepted medical use in treatment in the United States; and that the abuse of marijuana may lead to moderate or low physical dependence or psychological dependence. In addition, we urge DEA to acknowledge that 38 states, the District of Columbia, and four territories have legalized the use of medical marijuana to treat a myriad of health conditions.

For nearly three decades, states have recognized the safety and medical utility of this plant in addressing numerous qualifying health conditions under state medical marijuana laws and have accordingly abandoned prohibition in order to ensure patient access to medical marijuana. Today, approximately three-in-four Americans live in a state that has a regulated medical marijuana market and more than half reside in a state where marijuana is legally available to adults.

Within NCIA's membership, there are dozens of business professionals that can attest to how these programs successfully provide an alternative to the criminal market and how such alternatives advance public health goals through sensible regulation and consumer safety protocols.

Impact on Current State Marijuana Programs

Our organization, on behalf of our hundreds of member-businesses, seeks to participate in a hearing and formal rulemaking process to the fullest possible extent to provide insights regarding the Proposed Rule's myriad effects on the state-legal, regulated marijuana marketplace.

NCIA is prepared to testify on the importance of ensuring that any change to federal marijuana policy does not disrupt these state programs. Reclassifying marijuana to Schedule III without consideration of these successful state programs would have a profoundly negative impact on small marijuana businesses; many of which are women, veteran, and/or minority owned. Further, any disruption to these state markets would also undoubtedly adversely affect thousands of ancillary businesses that do not handle marijuana but provide products and services to state-licensed marijuana operators, cause a cascading loss of jobs and tax revenue across the country, and force consumers back into the unregulated, illicit market.

International Treaty Obligations

A substantive section of NCIA's comments filed in response to the NPRM outline how the reclassification of marijuana to Schedule III may impact the United States' international treaty obligations. Specifically, our organization's experts seek to provide DEA with testimony on how federal recognition of state marijuana markets would be entirely consistent with the purposes of the CSA and allow the DEA to shepherd state-regulated markets into "[*compliance*] with the United States' international obligations," while also "*ensuring that medically useful drugs remain available for legitimate purposes*" to medical marijuana patients who obtain their marijuana through state-regulated medical and adult use marijuana markets.

Economic Impact

Keeping marijuana in Schedule I or II would adversely impact almost all of NCIA's members. Conversely, moving marijuana to Schedule III would provide clear, profound, and increased economic benefits to the tens of thousands of businesses operating legally under state laws and to the communities which rely upon the tax revenue and jobs those businesses provide.

Our organization seeks to provide testimony on the positive economic impact of moving marijuana to Schedule III or lower. Specifically, our organization wishes to provide detailed information on how the proposed rule would provide tax parity for cannabis businesses by ensuring state-legal marijuana businesses are no longer subjected to Internal Revenue Code Section 280E, which prohibits businesses engaged in the "trafficking" of Schedule I or Schedule II controlled substances from deducting normal business expenses, such as payroll, rent, and the cost of compliance with state laws from gross income.

Lifting the unfair burden of 280E for businesses engaged in state-legal cannabis activities would generate additional taxable revenue through expanded business operations (growth in existing state-legal companies), promote new business formation, as well as curtail noncompliance. All of these factors would drive significant growth in jobs and state and federal income taxes and strengthen public health.

Considerations with the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Within NCIA's membership are a number of experts who can provide DEA and the ALJ invaluable information on the impact the Proposed Rule would have on state regulatory programs and the FD&C Act. Specifically, our organization wishes to expound upon the need for a statutory carve-out from the FD&C Act definition for "whole plant" cannabis and what the implications of doing so may be in areas such as medical research, interstate commerce, and regulatory enforcement.

Definitions and Categorizing Cannabinoids within the CSA

Our organization stands ready to provide expert testimony on our opposition to the proposed revisions to the definition of "Tetrahydrocannabinols" under DEA regulations, which could classify previously unscheduled cannabinoids as tetrahydrocannabinols (including, but not limited to, therapeutically beneficial and non-intoxicating cannabinoids like CBD, THCV and THCA when synthetically produced). As such, we respectfully ask to appear at the December 2 hearing to urge DEA to revise the definition of "Tetrahydrocannabinol" under 21 CFR § 1308.11 to address any potential confusion over the definition and its application to other non-scheduled cannabinoids without a formal scheduling action as required under the Controlled Substances Act at 21 USC §811(a).

Our concern is driven by the DEA's recent pronouncements, which suggest that the DEA may well apply its proposed regulation to lawful non-scheduled synthetically-derived non-intoxicating cannabinoids. In a letter from Terry Boos, Chief of the Drug & Chemical Evaluation Section of Diversion Control Division of the DEA, dated May 13, 2024, Dr. Boos communicated the DEA's statutory interpretation of both 21 U.S.C. § 812, Schedule I(c)(17) of the CSA and Section 7 U.S.C. 1639o of the Agriculture Improvement Act of 2018, Public Law 115–334 (the "2018 Farm

Bill”), concluding that “cannabis-derived THCA does not meet the definition of [federally legal] hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9-THC,” and “[t]he CSA classifies tetrahydrocannabinols (such as THCA) as controlled in schedule I” (emphasis added). Respectfully, this would be contrary to Congress’ intent in scheduling THC, and settled law per valid federal Circuit Court precedents.

We refer the DEA to the comment² submitted via regulations.gov by NCIA Policy Co-Chair and past Board Chair, Khurshid Khoja, for our suggested revisions to the proposed definition of tetrahydrocannabinols.

Conclusion

As the largest and longest-running trade association speaking for the legal cannabis industry, NCIA is uniquely positioned to provide expert input and testimony in all of the areas noted above. Our organization would also welcome the opportunity to elaborate on the topics outlined in our previously filed comments on the NPRM.

All notices and correspondence to be sent pursuant to this appearance should be addressed to the individuals noted below.

Respectfully,

Aaron Smith

CEO & Co-Founder
National Cannabis Industry Association
3845 Tennyson Street
Suite 170
Denver, CO 80212
aaron@thecannabisindustry.org

Michelle Rutter Friberg

Director of Government Relations
National Cannabis Industry Association
3845 Tennyson Street
Suite 170
Denver, CO 80212
michelle@thecannabisindustry.org

² Khoja, Khurshid. “Greenbridge Rescheduling Comment on Proposed Definition of Tetrahydrocannabinol.” *Www.regulations.gov*, 4 June 2024, www.regulations.gov/comment/DEA-2024-0059-11048. Accessed 30 Sept. 2024.



NATIONAL SHERIFFS' ASSOCIATION

Date: September 30, 2024

Drug Enforcement Administration, Attn: Administrator at nprm@dea.gov

Subject: Notice of Appearance of the National Sheriffs' Association
Drug Enforcement Administration
Possible Rescheduling of Marijuana
Docket No. DEA-1362

Dear Sir or Ma'am:

Please take notice that the National Sheriffs' Association will appear in the matter of the DEA's possible rescheduling of marijuana, Docket No. DEA-1362.

(A) (State with particularity the interest of the person in the proceeding.).

As a trade association, the National Sheriffs' Association represents hundreds of member sheriffs across the nation. Sheriffs (1) supervise the majority of the county jails in the country, (2) help enforce traffic laws, and (3) help respond to traffic accidents. In addition, some sheriff's offices (4) send deputies to participate in federal task forces, or they (5) cooperate with federal law enforcement, such as the DEA, on specific operations. Some of these are part of the DEA's mission to control diversion and help regulate research with controlled drugs and substances. *See* DEA, Researcher's Manual, 7–8 (rev. 2022).

NSA and its members are interested persons in DEA's NPRM to reschedule marijuana from schedule I to III of the CSA. *See* DEA, NPRM, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (May 21, 2024). A rule that moves marijuana to CSA schedule III will adversely affect or aggrieve NSA and its members. Reducing restrictions will increase the number of persons with marijuana intoxication and the degree of their intoxication in public and on the roads. This will increase the enforcement burden and the burden to respond to traffic accidents. It will increase the number of arrests and the number of persons coming to the county jail. Caring for intoxicated persons, including processing and withdrawal care, requires more time and effort from detention and medical staff. In addition, reducing restrictions on marijuana will complicate DEA's diversion-and-control efforts and expose local communities to the risks that the DEA's program is designed to combat.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

1. Overall, NSA and its members object to DEA's proposal to move marijuana from CSA schedule I to III.

2. NSA and its members object to DEA's proposal to move marijuana as a whole to schedule III. When Congress put marijuana in schedule I in 1970, it created no category problems because it prohibited all of its components. But moving *all* components of marijuana (save hemp) to schedule III or a lower schedule ignores the fact that cannabis contains hundreds of compounds, including Δ^9 THC and CBD (from which

Δ 8 THC is derived).¹ Rescheduling marijuana as a whole commits the fallacy of composition (assuming that something is true for the whole because it is true of a part) and is inconsistent with sound scientific or medical reasoning. HHS and DEA should study and make scheduling decisions for individual components of the plant *Cannabis sativa* L. For comparison, the poppy plant, *Papaver somniferum*, is “the key source for many narcotics, including morphine, codeine, and heroin.”² Heroin, for example, is on schedule I and morphine is on II.³

3. NSA and its members object to DEA’s proposal to move marijuana to schedule III, regardless of the concentration of psychoactive components like Δ 9 THC or Δ 8 THC. Products or compounds with codeine, for comparison, may be in schedule III or V, depending on concentration.⁴

4. HHS’s conclusion that there exists some credible scientific support for the use of marijuana for anorexia related to a medical condition, nausea and vomiting (*e.g.*, related to chemotherapy), and pain (CAMU) commits the fallacy of composition. Even if it is true that there exists some credible scientific support for the medical use of *some component* of the plant *Cannabis sativa* L., it does not follow that similar support exists to conclude that marijuana, as complex whole, has a CAMU for these purposes.

5. Even crediting HHS’s reasoning about a CAMU in its August 29, 2023 *Basis for Recommendation*, its reasoning does not support moving marijuana from I to III as opposed moving it to II. A CAMU is necessary for movement to either schedule.

6. As HHS and DEA have concluded in years past, marijuana has a high potential for abuse, and this precludes its placement in schedule III. NSA and its members object to DEA’s contrary proposal.

7. In its *Basis*, HHS failed to consider whether marijuana has a high potential for abuse. It considered only its relative abuse potential. NSA and its members object to this legal error (erroneous reading of the CSA).

8. HHS’s reasoning about marijuana’s relative abuse potential is suspect and unscientific. Since 2016, the industry has developed marijuana strains and products with higher and higher concentrations of Δ 9 THC, and abuse potential turns significantly on potency.

9. Second, HHS ignored abundant epidemiological evidence about marijuana’s high abuse potential, and HHS considered only a slice of this evidence and put the most weight on evidence about relative adverse outcomes. HHS offered no reason for this change in focus, much less a reason that impeached its past reasoning. For example, HHS pointed to no evidence that marijuana’s adverse outcomes are lower relative to schedule I and II drugs now than in years past.

¹ See Erin M. Rock & Linda A. Parker, “Constituents of Cannabis Sativa, *Adv Exp Med Biol.* 2021; 1264:1–13, (“There are more than 550 chemical compounds in cannabis, with more than 100 phytocannabinoids being identified, including Δ 9-tetrahydrocannabinol (THC) and cannabidiol (CBD).”), [https://pubmed.ncbi.nlm.nih.gov/33332000/#:~:text=There%20are%20more%20than%20550,%20and%20cannabidiol%20\(CBD\).](https://pubmed.ncbi.nlm.nih.gov/33332000/#:~:text=There%20are%20more%20than%20550,%20and%20cannabidiol%20(CBD).)

² DEA, Drug Fact Sheet, “Opium” (Apr. 2020), <https://www.dea.gov/factsheets/opium#:~:text=Opium%20is%20a%20highly%20addictive,morphine%2C%20codeine%2C%20and%20heroin.>

³ See 21 CFR § 1308.11, § 1308.12.

⁴ See 21 CFR § 1308.13(e) (codeine-containing products in III), § 1308.15(c)(1)&(2) (codeine-containing products in V).

10. Third, HHS's conception of adverse outcomes is unscientifically narrow as well. HHS considered chiefly serious medical outcomes, including death, visits to emergency departments, hospitalizations, unintentional exposures, and overdose deaths. That is, HHS considered single-dose adverse consequences while ignoring or discounting evidence of marijuana's long-term dangers to individual and public health. NSA and its members object to DEA's and HHS's errors or missteps in objections 7, 8, and 9.

11. HHS made similar missteps in not finding that marijuana may lead to severe psychological or physical dependence. The evidence that marijuana use or abuse is growing across age groups and demographics domestically and globally is overwhelming, and 3 in 10 people who use cannabis have cannabis use disorder. NSA and its members object.

12. NSA and its members incorporate its objections and arguments in its Comments on FR Doc # 2024-11137, submitted July 22, 2024, in response to NPRM 89 FR 44597 (comment ID DEA-2024-0059-42258).

(C) (State briefly the position of the person with regard to the particular objections or issues.).

1. NSA and its members oppose DEA's proposal to move marijuana from CSA schedule I to III.

2. NSA and its members object to DEA's proposal to treat marijuana, as the CSA defines it, as one thing, and they contend that DEA should make scheduling decisions for individual components of the plant *Cannabis sativa L.* similar to scheduling for components of the poppy plant.

3. Similarly, NSA and its members object to DEA's proposal to reschedule all of marijuana to III, regardless of the concentration of psychoactive components, like $\Delta 9$ and $\Delta 8$ THC. They contend that scheduling decisions should consider concentration, like those for products containing codeine.

4. NSA and its members object to HHS's conclusion about marijuana and a CAMU. Regardless of the credible support that a component of marijuana may have a CAMU, it does not follow that marijuana itself has a CAMU. Even crediting HHS's reasoning about a CAMUS, it does not support moving marijuana to III, instead of II. Both II and III require a CAMU.

5. As HHS has concluded in years past, marijuana has a high potential for abuse. NSA and its members object to HHS's failure to find this in its 2023 *Basis*. NSA and its members object to HHS's legal error of failing to consider whether marijuana has a high potential for abuse. HHS considered only marijuana's abuse potential relative to that of schedule I and II drugs.

6. NSA and its members object that HHS's reasoning about marijuana's relative abuse potential is unscientific as well. The industry has developed marijuana strains and products with higher $\Delta 9$ -THC potency, and they object to HHS's contrary conclusion disguised as a conclusion about marijuana's abuse potential relative to that of schedule I and II drugs.

7. Second, HHS ignored epidemiological evidence about marijuana's high abuse potential, by considering only a slice of this evidence and putting most weight on evidence about relative adverse outcomes. NSA and its members object that HHS offered no reason for this change, much less one that impeached its reasoning in years past. For example, HHS pointed to no evidence that marijuana's adverse outcomes are lower relative to those of schedule I and II drugs now than in past years.

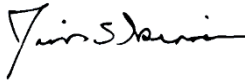
8. Third, using an unscientifically narrow conception of adverse outcomes, HHS considered chiefly serious medical outcomes, including death, ED visits, hospitalizations, unintentional exposures, and overdose deaths. That is, HHS considered single-dose adverse consequences while ignoring or

discounting evidence of marijuana's long-term dangers to individual and public health. As to individual health, evidence connects marijuana use to more frequent bronchitis episodes and worse respiratory symptoms; increased risks of schizophrenia, other psychoses, social anxiety disorders, and cannabis-use disorder; and it impairs learning, memory, and attention. Frequent use increases the risk of heart attack and stroke. Among young people, marijuana use is associated with impairments in cognition, worse academic or vocational outcomes, and increased prevalence of psychotic, mood, and addictive disorders. Marijuana impairs the ability to drive and contributes to motor-vehicle accidents and deaths. NSA and its members object to HHS and DEA overlooking these longer-term risks.

9. HHS made similar missteps in not finding that marijuana may lead to severe psychological or physical dependence. The evidence that marijuana use or abuse is growing across age groups and demographics domestically and globally is overwhelming, and 3 in 10 people who use cannabis have cannabis use disorder. NSA and its members object to these flaws in HHS's reasoning.

All notices to be sent pursuant to this appearance should be addressed to:

Sheriff Jim Skinner, Collin County, Texas
Secretary, National Sheriffs' Association
1450 Duke Street
Alexandria, Virginia, 22314
sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org



Nicholas Barreto

400 W. South Boulder Rd. #17
Louisville, CO 80027
9/30/2024

Drug Enforcement Administration

Attn: Administrator
8701 Morrisette Drive
Springfield, VA 22152

Subject: Notice of Appearance – Schedules of Controlled Substances: (Docket Number DEA-2024-0059)

Dear Administrator,

Please take notice that Nicholas Barreto will appear in the matter of the scheduling of cannabis under the Controlled Substances Act (CSA), specifically concerning **Docket Number DEA-2024-0059**.

(A) Interest in the Proceeding:

Interest Statement:

As a stage 4 cancer patient who has battled testicular cancer for over five years, I utilize marijuana medically to manage symptoms such as pain and nausea associated with my condition. Before my diagnosis, I relied on marijuana therapeutically to unwind after demanding work hours. It provided a safe and effective alternative to the harmful environments fostered by alcohol and tobacco, both of which are addictive substances known for their health risks.

I have witnessed friends fall into addiction from pharmaceuticals such as Xanax and opioids, as well as alcohol and cigarettes. In their struggles, I have seen marijuana serve as an Exit Strategy from these dangerous, socially accepted substances, allowing them to transition from rock-bottom lives to finding quality of life and relief.

In the United States, alcohol consumption is widespread and socially accepted in numerous venues, including aquariums, water parks, stadiums, art galleries, and festivals. This normalization makes it almost impossible to escape its presence, despite extensive research highlighting its risks, including addiction, liver disease, and various forms of cancer. Similarly, tobacco use is associated with significant health issues, including respiratory diseases and cancer, yet remains legally available and socially accepted.

Marijuana, on the other hand, has been used for medicinal purposes for thousands of years, with evidence dating back to ancient civilizations in Asia and Africa. However, it was placed on the scheduling list as a political tool, and the evidence supporting this claim is overwhelming. Its

classification as a Schedule I substance under the Controlled Substances Act implies a high potential for abuse and no accepted medical use—a designation that does not reflect the current understanding of marijuana as a therapeutic agent.

Now that we are using marijuana safely and building social acceptance, it is essential that access to this plant be granted to the people, not to Big Pharma, which has lobbied to keep individuals from accessing it. The push to reschedule marijuana to Schedule III is primarily motivated by corporate interests looking to profit from a substance that many have safely used for years. This is especially concerning given that many individuals are still imprisoned for non-violent crimes related to marijuana.

Providing access to marijuana empowers individuals to choose safer alternatives for relaxation and symptom management, while simultaneously serving as an Exit Strategy for those struggling with addiction to more harmful substances. I firmly believe that individuals should have the autonomy to choose their treatment options, including the right to grow their own marijuana and use it for healing without the interference of profit-driven pharmaceutical companies.

This proceeding is an opportunity to advocate for the rights of patients like myself, who seek safe and effective alternatives to address their health needs, and to call for a change that prioritizes the health and well-being of individuals over corporate profits

(B) Objections or Issues to Be Heard:

I object to the rescheduling of cannabis under the Controlled Substances Act and specifically wish to be heard on the following issues:

1. The Perils of Corporate Cannabis:

The cannabis industry, as currently shaped by prohibition, has allowed corporate interests and large businesses to dominate, often prioritizing profit over patient safety. There have been countless reports of contamination, unsafe growing practices, and harmful additives making their way into the market under the guise of regulation. Patients deserve the right to know exactly what is going into their medicine. Rescheduling, while addressing some issues, will continue to force individuals to depend on corporations that do not always have their best interests at heart. True reform must allow people to grow their own cannabis—a personal right to cultivate medicine that they know is pure and safe. Descheduling is the only pathway to guarantee that patients and consumers have the freedom to grow and access clean, unadulterated cannabis.

2. Medical Access and Equity:

Rescheduling alone will not address the medical needs of millions who rely on cannabis. The federal restrictions placed on Schedule II substances still prevent access for many, particularly low-income patients and those in states where cannabis remains illegal. By keeping cannabis within any schedule, the law continues to criminalize and marginalize those who should be

protected, including communities of color that have been disproportionately targeted by the War on Drugs. Descheduling would end this harm and allow states to regulate cannabis without the looming threat of federal interference, ensuring that every patient, no matter where they live, can access the care they need.

3. Public Health and Safety:

It's time to shift the conversation about cannabis from fear and control to public health and harm reduction. Current corporate-driven models risk the safety of consumers, with varying standards across states and even more concerns with unregulated, illicit markets. If individuals are allowed to grow their own cannabis, they are empowered to take control of their health and ensure the purity of their product, much like growing one's own vegetables for safety from pesticides. Home cultivation is a right that ensures patients can trust the medicine they rely on, free from corporate manipulation or contamination. The prohibition of home-growing keeps people reliant on a system that too often fails them.

Position on the Issues:

I advocate for the descheduling of cannabis as the only comprehensive solution to the public health, criminal justice, and safety concerns currently surrounding cannabis prohibition.

People should be able to grow their own cannabis, ensuring that they have full control over what goes into their medicine. The horrors of contaminated products from big cannabis corporations have shown that true safety lies in self-cultivation. Individuals should not have to rely on large, profit-driven companies to provide safe medicine when they can cultivate it themselves.

Full descheduling removes federal barriers and allows states to craft cannabis laws that serve their populations without conflicting legal requirements. It will ensure that low-income and marginalized patients have access to affordable, safe cannabis, rather than relying on expensive, corporate-driven products or risking unsafe, unregulated markets.

Descheduling cannabis is crucial to ending the criminalization of communities of color and low-income individuals who have borne the brunt of prohibition. The rescheduling of cannabis will not stop the criminal justice disparities or the criminal penalties that have caused untold damage to families across the country. Descheduling is the only solution that allows for full criminal justice reform, eliminating federal criminal penalties, expunging records, and allowing economic opportunities to thrive in a legal and regulated industry.

Descheduling¹ vs. Rescheduling Clarification:

Rescheduling: Moving cannabis from Schedule I to a less restrictive category (such as Schedule II or III) under the CSA. This would still keep cannabis under strict federal control, limiting access and failing to address the broader public health, social justice, and economic issues tied to prohibition.

Descheduling¹: Completely removing cannabis from the schedules of the CSA. This action would eliminate federal control over cannabis, allowing individuals to grow their own cannabis, ensuring full medical access, and ending the criminal penalties that continue to harm communities. Descheduling is the only way to ensure real, lasting reform.

All notices to be sent pursuant to this appearance should be addressed to:

Nicholas Barreto
400 W. South Boulder Rd. #17
Louisville, CO 80027

Respectfully,
Nicholas Barreto
Nicholas Barreto



Nick Richards, Partner
1144 15th Street, Suite 2700
Denver, Colorado 80202
Phone: 303.665.0860

9/30/2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Greenspoon Marder, LLP % Nick Richards, Esq.

1141 15th Street, Suite 2700

Denver, CO 80202

Subject: Notice of Appearance

DEA:

Please take notice that Attorney Nick Richards will appear in the matter of: Docket No. DEA-1362.

Mr. Richards is an attorney and former IRS attorney who qualifies as an interested and adversely affected person through his representation of many legal cannabis companies and company owners before the Internal Revenue Service beginning first in 2014 and ongoing through today. These individuals, families and companies have been harmed by the imposition of tax Section 280E and the proposed rescheduling will not provide relief for the crushing tax debt they face.

A) Mr. Richards will speak to the unfair impact Section 280E has on affected persons, explain the IRS history of enforcing Section 280E against honest and often unknowing taxpayers, and explain the problem the IRS has collecting 280E tax liabilities

B) Mr. Richards will suggest resolutions to the Section 280E problems including collection alternatives, safe harbor programs, and a common-sense resolution to the “phantom income” that Section 280E causes.

C) Mr. Richards will speak about the impacts of the Schedule III status change and appropriate paths for relief for the cannabis industry. Mr. Richards will speak in favor of moving Cannabis to Schedule III and will also speak to the benefits of fully de-scheduling Cannabis and to treat it more like alcohol as many state regimes have intended to do.

All notices to be sent pursuant to this appearance should be addressed to:

Nick Richards (Nick.Richards@gmlaw.com is also acceptable)

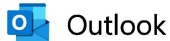
1144 15th St., Suite 2700

Denver, CO 80218

Respectfully yours,



Nick Richards, Esq



Outlook

[EXTERNAL] Docket No. DEA-1362 - Written Notice of Desired Participation - Nick Richards

From Deena Lawrence <Deena.Lawrence@gmlaw.com>**Date** Mon 9/30/2024 3:35 PM**To** NPRM <NPRM@dea.gov>**Cc** Nick Richards <Nick.Richards@gmlaw.com>; Ben Gelt <Ben.Gelt@gmlaw.com>; Sarah Burton <Sarah.Burton@gmlaw.com>

1 attachment (99 KB)

Docket No. DEA-1362 - Written Notice of Desired Participation - Nick Richards.pdf;

To whom it may concern,

I am emailing on behalf of Attorney Nick Richards regarding his written notice of desired participation for the DEA hearing scheduled for December 2.

Attached please find his written notice of desired participation.

If you have any questions or anything else is required from our end for Nick, please do not hesitate to contact me.

Thank you,
Deena

GreenspoonMarder_{LLP}**Deena Lawrence**

Greenspoon Marder LLP

Senior Marketing Program Manager

200 East Broward Boulevard, Suite 1800

Fort Lauderdale, FL 33301

Direct Phone Number: 954.527.2454

Office Phone Number: 954.491.1120

Cell Phone Number: 954.224.1392

Deena.Lawrence@gmlaw.comwww.gmlaw.com**GREENSPOON MARDER LLP LEGAL NOTICE**

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A portion of our practice involves the collection of debt and any information you provide will be used for that purpose if we are attempting to collect a debt from you.

THE LAW OFFICES OF

J O S E P H A . B O N D Y

JOSEPH A. BONDY

1776 BROADWAY, STE. 2000
NEW YORK NY 10019
TEL 212.219.3572
JOSEPHBONDY@MAC.COM

September 30, 2024

(filed electronically at: nprm@dea.gov)

Drug Enforcement Administration

Attn: Administrator

8701 Morrisette Drive

Springfield, Virginia 22152

Drug Enforcement Administration

Attn: Hearing Clerk/OALJ

8701 Morrisette Drive

Springfield, Virginia 22152

Drug Enforcement Administration

Attn: DEA Federal Register

8701 Morrisette Drive

Springfield, Virginia 22152

Re: Notice of Intention to Participate in Hearing and Notice of Appearance
Rescheduling of Marijuana, Docket No. DEA-1362

Dear Administrator Milgram:

The National Organization for the Reform of Marijuana Laws (NORML), as an “interested person,” respectfully files the instant Notice of Intention to Participate in a Hearing for the Rescheduling of Marijuana¹ and Notice of Appearance, pursuant to 21 C.F.R. §§ 1308.44(b) and 1316.48.

For the past 54 years, NORML’s mission has been to move public opinion sufficiently to legalize the responsible use of cannabis by adults, and to serve as an advocate for cannabis consumers to ensure they have access to high-quality cannabis that is safe, convenient, and affordable. NORML supports removing cannabis entirely from the Controlled Substances Act (CSA). Today, NORML remains the world’s largest and best-known cannabis consumer advocacy organization, with over 1.2 million social media followers and a weekly e-mail news distribution of over 300,000.

NORML has standing to participate in the administrative hearing, and the expert witnesses proffered have significant expertise and understanding of core issues ranging from the medical

¹ Hereinafter “cannabis.”

efficacy and low potential for abuse of cannabis to the economic consequences of rescheduling for consumers and businesses.

I. Notice of Proposed Rulemaking and Hearing

On May 21, 2024, the Department of Justice (DOJ) published a notice of proposed rulemaking (NPRM) to transfer cannabis from schedule I to schedule III of the CSA, accordant with the findings of the Department of Health and Human Services (HHS) that cannabis has a currently accepted medical use and a potential for abuse less than the drugs or other substances in schedules I and II.

On August 26, 2024, after having reviewed the public comments and requests for an administrative hearing, you authorized a hearing to be conducted in accordance with the Administrative Procedure Act 5 U.S.C. §§ 551-559, the CSA 21 U.S.C. § 811, *et seq.*, and the DEA regulations.

The hearing is currently scheduled to commence on December 2, 2024, at 9:00 a.m. at the DEA Hearing Facility, 700 Army Navy Drive, Arlington, VA 22202, pursuant to the provisions of 5 U.S.C. §§ 556 and 557, and 21 C.F.R. §§ 1308.41-45, and §§ 1316.41-1316.68.

Pursuant to 21 U.S.C. §§ 811 and 812, the scope of the hearing is to “receiv[e] factual evidence and expert opinion regarding” whether cannabis should be transferred to schedule III of the list of controlled substances. 21 C.F.R. § 1308.42.

All interested persons—defined under 21 C.F.R. § 1300.01(b) as “any person adversely affected or aggrieved by any rule or proposed rule issuable” under 21 U.S.C. §811—who wish to participate in the hearing may file an electronic notice of intention to participate for review by the Agency on or before 11:59 p.m. Eastern Time on September 30, 2024.

II. History of NORML

Since its founding in 1970, NORML has provided a voice in the public policy debate for those Americans who oppose cannabis prohibition and favor an end to the practice of arresting otherwise law-abiding cannabis consumers.

A nonprofit public-interest consumer advocacy group, NORML represents the interests of the tens of millions of Americans who use cannabis responsibly and believe the recreational and medicinal use of cannabis should no longer be a crime. NORML supports the removal of all criminal and civil penalties for the private possession and responsible use of cannabis by adults, including the cultivation for personal use and the casual nonprofit transfer of small amounts.

During the 1970s, NORML led successful efforts to decriminalize minor cannabis offenses in eleven states and significantly lower cannabis penalties in others.

Today, NORML continues to lead the fight to reform state and federal cannabis laws, whether by voter initiative or through the elected legislatures. NORML serves as an informational

resource to the [national media](#) on cannabis-related stories; lobbies state and federal legislators in support of reform legislation; publishes a regular [newsletter](#); hosts, along with The NORML Foundation, an informative website; maintains a National Legal Committee comprised of several hundred attorneys; conducts CLE-accredited [NORML Legal Seminars](#), and; serves as the umbrella group for a national network of citizen-activists committed to ending cannabis prohibition and legalizing cannabis.

NORML's sister organization, [The NORML Foundation](#), sponsors public awareness campaigns to better educate the public about cannabis and alternatives to current cannabis policy; provides legal assistance and support to victims of the current laws; and undertakes relevant research.

NORML maintains its offices in Washington, DC, and has a nationwide network of volunteer state and local [NORML Chapters](#).

III. NORML has Standing to Participate

For over fifty years, NORML has been recognized to have associational standing to be heard at DEA administrative hearings on the rescheduling of cannabis.

In 1972, NORML filed its first petition for review of the DEA Acting Administrator's order regarding the rescheduling of cannabis. When DEA refused to hear the petition, NORML appealed, and the D.C. Circuit remanded the case for further proceedings, including a hearing to determine the regulatory controls necessary to satisfy international treaty obligations. *National Organization for the Reform of Marijuana Laws (NORML) v. Ingersoll*, 497 F.2d 654 (D.C. Cir. 1974). When the DEA then published a notice in the *Federal Register* announcing that it was prepared to hold such a hearing, NORML and the American Public Health Association requested a "phase one" hearing on the question of whether separated leaves and seeds of cannabis could be removed from schedule I, which was held before an Administrative Law Judge in 1975. *National Organization for the Reform of Marijuana Laws (NORML) v. DEA, U.S. Dep't of Justice*, 559 F.2d 735 (D.C. Cir. 1977).

Since that time, NORML's standing on this subject has been presumed. *See, e.g., United States v. Creswell*, 525 F. Supp. 1268 (E.D.N.Y. 1981) (citing NORML's earlier rescheduling petition without questioning that it had standing). Moreover, the recent DEA Notice of Proposed Rulemaking itself, Docket No. DEA-1362; A.G. Order No. 5931-2024 Schedules of Controlled Substances: Rescheduling of Marijuana (May 16, 2024), twice cites *Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735 (D.C. Cir. 1977), without questioning NORML's standing. *See* Notice of Proposed Rulemaking at pp 8 and 84, fn. 39.

NORML plainly satisfies well-settled criteria for associational standing. *See Coalition of Human Advocates for K9's & Owners v. City & County of San Francisco*, 2007 U.S. Dist. LEXIS 18820 (N.D. Cal. 2007). Associational standing requires that an organization demonstrate three elements: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted, nor the relief requested requires the participation of individual members in the lawsuit.

See *Biafra v. Antony Blinken, Sec'y of State*, 639 F. Supp. 3d 79 (D.D.C. 2022), *Day v. Sebelius*, 376 F. Supp. 2d 1022 (D. Kan 2005).

First, NORML's members would have standing to sue in their own right because the proposed rescheduling of cannabis directly impacts their health, legal status, and economic interests. The injury is concrete and particularized, as it affects these individuals' health and legal status. *Nulankeyutmonen Nkihtaqmikon v. Impson*, 462 F. Supp. 2d 86 (D. Me. 2006), *Carello v. Aurora Policemen Credit Union*, 930 F.3d 830 (7th Cir. 2019). This meets the requirement that at least one member possesses standing to sue in their own right.

Second, the interests NORML seeks to protect are germane to its very purpose. NORML's mission is to advocate for the reform of cannabis laws and protect the rights of cannabis consumers. The proposed rescheduling of cannabis falls squarely within this mission, as it directly impacts the legal status and rights of cannabis consumers. This satisfies the requirement that the interests the suit seeks to vindicate are germane to the association's purpose.

Third, neither the claim asserted, nor the relief requested requires the participation of individual members in the lawsuit. *McKinney v. United States Dep't of Treasury*, 799 F.2d 1544 (Fed. Cir. 1986), *Reid v. Department of Commerce*, 793 F.2d 277 (Fed. Cir. 1986). The nature of the claim and the relief sought do not make the individual participation of each injured party indispensable to the proper resolution of the cause, thus meeting the third prong of the associational standing test.

Moreover, NORML's robust historical involvement in cannabis regulation further supports its standing. See *National Organization for Reform of Marijuana Laws (NORML) v. Bell*, 488 F. Supp. 123, fn. 3 (D.D.C. 1980). This repeated historical involvement in cannabis rescheduling petitions underscores NORML's expertise and commitment to the issue, making it a valuable and critically important participant in the upcoming hearing.

NORML's representation of its members and millions of other cannabis consumers, combined with its historical involvement and expertise, makes it uniquely positioned to provide essential testimony in this administrative hearing. The organization satisfies the criteria for "associational standing," ensuring that the interests and concerns of a significant portion of the public are adequately represented and considered in the decision-making process.

Finally, NORML also has "organizational standing," as it has suffered its own actual injury as a result of the Proposed Rule. Among other things, NORML invests professional and staff time, money, and other resources to advocate for state and federal legalization and cannabis consumers' access to safe and properly regulated legal markets, and the Proposed Rule has rendered many of these actions and expenditures nugatory.

IV. *Proposed NORML Testimony--Medical Use and Low Potential for Abuse, and the Economic Consequences of Rescheduling*

In support of NORML's request to participate in the upcoming administrative hearing, it proffers two cannabis expert witnesses on the core subjects of medical use and low potential for

abuse and the economic consequences of rescheduling. NORML is also prepared to proffer additional expert witness testimony as deemed relevant on issues including, but not limited to, criminal justice, cannabis' health and safety impacts, federal sentencing, and international treaty considerations.

A. Paul Armentano, NORML Deputy Director

Paul Armentano has three decades of experience working professionally in cannabis policy. He is currently the Deputy Director of NORML, for which he has worked in various capacities since the mid-1990s. For nearly two decades, he also served as a faculty member at Oaksterdam University, where he was the Chair of Science. He routinely lectures on matters specific to the efficacy and abuse potential of cannabis. Mr. Armentano's *curriculum vitae* is attached hereto as Exhibit A.

His writing on cannabis and cannabis policy has appeared in over 1,500 publications, scholarly or peer-reviewed journals, and more than two dozen textbooks and anthologies. Mr. Armentano is the co-author of the book *Marijuana is Safer: So Why Are We Driving People to Drink?* (2009, 2013: Chelsea Green), which has been licensed and translated internationally. He is also the author of the book *Clinical Applications for Cannabis and Cannabinoids* (2021: National Organization for the Reform of Marijuana Laws), which summarizes over 450 peer-reviewed studies specific to the safety and efficacy of cannabis among different patient populations.

Mr. Armentano routinely speaks on matters specific to the health effects of cannabis and the policy implications of legalization before various academic, medical, and legal audiences. He also has appeared in state and federal court as an expert witness in dozens of cannabis-related cases. Mr. Armentano was the principal investigator for defense counsel in the federal case *U.S. v Schweder et al.*, one of the only legal cases to challenge the constitutionality of cannabis as a Schedule I controlled substance. In November 2022, he spoke to members of the United States Congress, House of Representatives, Subcommittee on Civil Rights and Civil Liberties at a hearing titled, "Developments in State Cannabis Laws and Bipartisan Cannabis Reforms at the Federal Level."

Mr. Armentano has published peer-reviewed papers on the subject of cannabis-influenced psychomotor performance and accident risk. He has written about and commented publicly on tens of thousands of cannabis-related studies to hundreds of mainstream media outlets, including the New York Times, CNN, The Associated Press, C-SPAN, NPR, and others. He is the author of the NORML's recent public comments to DEA, attached hereto as Exhibit B, affirming that the available scientific evidence clearly shows that cannabis does not meet the necessary criteria of either a Schedule I or Schedule II controlled substance. In support of this conclusion, he cited dozens of scientific studies specific to various areas of interest to the Agency in the matter of rescheduling, including cannabis-related emergency room visits, the relationship between cannabis and mental health, and the impact of cannabis use on cognitive performance, among other issues. His decades of experience and work in this field make him qualified to provide "factual evidence and expertise" on these and other matters inherent to the issues before the administrative law judge.

B. Beau Whitney, Cannabis Economist

Beau Whitney is a cannabis economics, operations and supply chain expert. Mr. Whitney is the founder and Chief Economist at Whitney Economics, based in Portland, Oregon, and is a global leader in cannabis and hemp business consulting, data, and economic research. His *curriculum vitae* is attached hereto as Exhibit C.

Serving an international clientele, Mr. Whitney is considered one of the leading cannabis economists in the U.S. and globally. His applications of economic principles to create actionable operational and policy recommendations have been recognized by governments and throughout the economic, investment, and business communities. In 2022, Mr. Whitney presented data and insights about cannabis and hemp economics at the United Nations.

His white papers analyzing the adult-use, medical and industrial cannabis markets have been referenced in the Wall Street Journal, Washington Post, New York Times, USA Today, and the Associated Press, as well as in leading cannabis industry publications.

Mr. Whitney is a member of the American Economic Association and is the Oregon chapter president of the National Association for Business Economics. He is a member of multiple regulatory advisory committees throughout the U.S. and participates on the Oregon Governor's Council of Economic Advisors. Whitney Economics does not take a position on the legality of cannabis or pending legislation.

Proposed testimony by Mr. Whitney would include, but not necessarily be limited to:

- The potentially significant federal tax benefits of rescheduling for the cannabis industry, with projected additional taxes of \$2.4 billion in 2024, increasing to \$3.1 billion by 2026 and \$5.2 billion by 2030.
- That a reduction in costs through tax rate or interest rate reductions would stimulate the economy, with a multiplier effect of 2.4x in the cannabis industry, leading to an estimated \$5.8 billion stimulus in 2024 and increasing over time.
- The economic benefits from cannabis taxation reform would initially be utilized by businesses to reduce debt or pay off delinquent accounts payable, improving the financial health of the industry and reducing incentives for diversion into the illicit market.
- In the medium run, savings from improved financial health would be passed on to consumers through price reductions, leading to increased demand, sales, and subsequently increased federal and state tax revenues.
- Rescheduling cannabis would result in increased employment by cannabis operators to support the rise in demand, thereby boosting revenues for both state

and federal governments, while also helping regulators achieve public policy objectives and reducing state and federal expenditures.

Given his unique professional background and expertise as a cannabis economist, Mr. Whitney is imminently qualified to provide “factual assistance and expertise” on the economic consequences of rescheduling cannabis.

Conclusion

For the reasons set forth herein, NORML respectfully gives notice of its intent to participate in the upcoming administrative hearing to the fullest extent permitted by law. We believe NORML has well earned a seat at the table, and that it is in the public interest for it to be heard.

Respectfully submitted,

Joseph A. Bondy

Joseph A. Bondy

*(Vice-Chair, Board of Directors;
Counsel to NORML)*

Law Offices of Joseph A. Bondy

1776 Broadway

Suite 2000

New York, N.Y. 10019

(jab@josephabondy.com)

Exhibit A

PAUL ARMENTANO**paul@norml.org****Professional Experience**

- [Deputy Director](#), National Organization for the Reform of Marijuana Laws: 1995-1999, 2001-present
- [Faculty](#)/Chair of Science, Oaksterdam University: 2009-August 2022
- [Contributing Expert](#), TheHill.com/Capitol Hill Publishing Corp: 2016-present
- Faculty, The Lambert Center for the Study of Medicinal Cannabis and Hemp at Thomas Jefferson University: 2018-2019
- Content Provider, The Blade newspapers (Washington DC and Los Angeles): 2018-present
- Advisor, Guidepoint Global Advisors: 2017-present
- Advisor, GLG Research Insights: 2021-present
- Appointee, City of Vallejo, California: Medical Marijuana Stakeholders and Expert Group (task force): 2016-2017

Relevant Peer-Reviewed Publications

- Armentano. 2015. Are THC concentrations appropriate for presuming psychomotor impairment? In: Tiftickjian. Medicolegal Aspects of Marijuana: Colorado Edition. Tucson: Lawyers & Judges Publishing Company. pp. 131-135.
- Armentano, 2013. Should Per Se Limits Be Imposed for Cannabis? Equating Cannabinoid Blood Concentrations with Actual Driver Impairment: Practical Limitations and Concerns. *Humboldt Journal of Social Relations*, Issue 35, pp. 41-51.
- Armentano. 2012. Cannabis and Psychomotor Performance: A Rational Review of the Evidence and Implications for Public Policy. *Drug Testing & Analysis*, Volume 5, Issue 1, pp. 52-56.
- Armentano. 2010. Driving Under the Influence. In: Holland. The Pot Book: A Complete Guide to Cannabis, Its Role in Medicine, Politics, Science, and Culture. Toronto: Park Street Press. pp. 196-201.

Books

- Co-author. The Budtender's Guide: A Reference Manual for Cannabis Consumers and Dispensary Professionals (2022) Oaksterdam University.
- Clinical Applications for Cannabis (2021) Washington, DC: NORML Foundation
- The Citizen's Guide to State By State Marijuana Laws (2015) Atlanta, GA: Whitman Publishing
- Co-author. Marijuana Is Safer: So Why Are We Driving People to Drink? (2009, revised 2013) White River Junction, VT: Chelsea Green Press

Curricula

- [Cannabis, Pain, and the Opioid Crisis](#) (Oaksterdam University)

Chapters in Anthologies (partial list)

Mr. Armentano has authored chapters pertaining to the subject of cannabis, the law, health implications, and public policy for more than two-dozen anthologies and textbooks, including: The Politics of Marijuana: A New Paradigm (Peter Lang, 2019) Medicological Aspects of Marijuana: Michigan Edition (Lawyers & Judges Publishing, 2019), Medicological Aspects of Marijuana: Arizona Edition (Lawyers & Judges Publishing, 2018), Issues: Understanding Controversy and Society (2017: ABC-CLIO), The Medical Marijuana Dispensary (2016, Althea Press), The Legalization of Marijuana: Opposing Viewpoints (Greenhaven Press, 2016); Medicological Aspects of Marijuana: Colorado Edition (Lawyers & Judges Publishing, 2015); Marijuana: Opposing Viewpoints (Cengage/Thomas Gale, 2014); Addiction: Opposing Viewpoints (2014, Greenhaven Press); Drug Legalization (2014, Greenhaven Press); Medical Marijuana: Opposing Viewpoints (Greenhaven Press, 2013); Teen Rights and Freedoms: Search and Seizure (Greenhaven Press, 2013); Marijuana: Introducing Issues With Opposing Viewpoints (2012, Cengage Learning/Greenhaven Press); Think: Critical Thinking and Logic Skills For Everyday Life (McGraw Hill, 2011); Current Controversies: Medical Marijuana (Thomson Gale/Cengage Learning, 2011); (The Pot Book: A Complete Guide to Cannabis – Its Role in Medicine, Politics, Science, and Culture (Park Street Press, 2010); Marijuana (Thomson Gale/Cengage Learning, 2009); Teens at Risk: Opposing Viewpoints (Greenhaven Press, 2009); Gateway Drugs (Thomson Gale/Cengage Learning, 2008); Censored 2009: The Top 25 Censored Stories of 2007-08 (Seven Stories Press, 2008); Introducing Issues With Opposing Viewpoints: Marijuana (Thomson Gale/Cengage Learning, 2007); Drugs, Society & Behavior -- 20th Edition (McGraw Hill, 2005); The War on Drugs: Opposing Viewpoints (Thomson Gale/Cengage Learning, 2004); Police Brutality: Current Controversies (Greenhaven Press, 2004); You Are Being Lied To: The Disinformation Guide to Media Distortion, Historical Whitewashes and Cultural Myths (Disinformation Press, 2001); The New Prohibition

(Accurate Press, 2004); Busted: Stone Cowboys, Narco-Lords, and Washington's War on Drugs (Nation Books, 2002); and Drug Abuse: Opposing Viewpoints (Greenhaven Press, 1999)

Honors

- 2019 recipient: The Al Horn Award in Recognition of a Lifetime of Ceaseless Work to Advance Justice
- 2013 recipient: The Alfred R. Lindesmith Award for Achievement in the Field of Scholarship
- 2013 recipient: Freedom Law School Health Freedom Champion of the Year award
- 2008 recipient: Project Censored Real News Award for Outstanding Investigative Journalism
- 1995 recipient: Who Cares Magazine Young Visionaries Award

Legal

- Expert: *Allard et al v Her Majesty the Queen*. Canadian federal court, Vancouver: May 2015.
- Principle Investigator. Evidentiary hearing: *US v Schweder et al*. US federal court, Eastern District of California, Sacramento: October 25-30, 2014.

Relevant Presentations (partial list)

- Keynote Speaker: Annual Conference of the Cannabis Law Section of the State Bar of Michigan, Kalamazoo, MI, 2024. **CLE-accredited event**
- Plenary Speaker at: 2024 Missouri NORML Conference, Columbia, MO, 2024
- Plenary Speaker before the Colorado State Public Defenders, 2023. **CLE-accredited event**
- Plenary Speaker at: California Cannabis Control: Regulation, Code, and Enforcement, Sacramento, CA 2022.
- Plenary Speaker at: Annual Conference of the Cannabis Law Section of the State Bar of New Mexico, 2021. **CLE-accredited event**
- Plenary Speaker at: 2021 Missouri NORML Conference, Columbia, MO, 2021

- Oral and written testimony before members of the Nevada Assembly Committee on Judiciary in support of Assembly Bill 400 (March 29, 2021)
- Oral and written testimony before members of the Philadelphia City Council in support of Bill No. 200625 (APRIL 4, 2021)
- Plenary Speaker at: 2020 Employment and Law Labor Institute conference, sponsored by the New Mexico State Bar, 2020. **CLE-accredited event**
- Plenary Speaker at: 2020 Cannabis Law in New Mexico, Sponsored by the New Mexico State Bar Foundation, **CLE-accredited event**
- Plenary Speaker: At Marijuana Law Conference, 4th Annual, Sponsored by the Marijuana Law Section of the State bar of Michigan, Grand Rapids, MI, 2019. **CLE-accredited event**
- Plenary Speaker: At: John Muir Medical Center Cannabis Education Day, Sponsored by The San Francisco Bay Area Chapter of the Hospice and Palliative Nurses Association, Walnut Creek, CA, 2019. **CNE-accredited event**
- Keynote Speaker: At: Winning the War on the War on Drugs, Sponsored by The Ron Paul Institute for Peace and Prosperity, Houston, TX, 2019.
- Plenary Speaker: At: California Association of Criminalists Spring 2019 Seminar, Sponsored by the CAC and the Oakland Police Department Laboratory, Oakland, CA, 2019.
- Keynote Speaker: At: Adaptive Business Leaders Executive Round Table, Sponsored by the ABL Organization of San Francisco, San Francisco, CA, 2018.
- Plenary Speaker: At: New Horizons for Medical Marijuana. Sponsored by the Michigan State Bar. Detroit, MI. 2017. **MCLE-accredited event**
- Plenary Speaker: At: 2nd International Symposium on Medical Cannabis Therapeutics. Sponsored by Dartmouth-Hitchcock Medical School. Manchester, NH. 2017. **CME-accredited event, CNE-accredited event**
- Keynote Speaker: At: Marijuana – What Every Lawyer Must Know. Sponsored by the Michigan State Bar. Battle Creek, MI. 2016
- Keynote Speaker. At: Green Flower Media live broadcast. Los Angeles, CA. 2016.

- Plenary Speaker. At: 2016 DUIDLA Summer Seminar. Sponsored by the DUI Defense Lawyers Association: Denver, CO. 2016.
- Keynote Speaker. At: 2016 Holistic Cannabis Summit. Denver, CO. 2016
- Keynote Speaker. At: The Citadel. Charleston, SC. 2016
- Plenary speaker. At: MIAOWIA 2015 Spring Seminar. Sponsored by Michigan Association of OWI Attorneys: East Lansing, MI. **MCLE-accredited event.**
- Plenary Speaker. At: Marijuana DUI, San Francisco, CA. Sponsored by UCLA Continuing Education of the Bar: San Francisco, California. 2015. **MCLE-accredited event**
- Plenary Speaker. At The Business of Cannabis, Oakland, CA. Sponsored by World's Presidents Organization (WPO) San Francisco, WPO Northern California, WPO Santa Barbara, and Young Presidents Organization (YPO) Santa Barbara. 2015.
- Plenary speaker. At: Symposium on Medical Cannabis Therapeutics, Lebanon, NH, 2014. Sponsored by Dartmouth University and the Dartmouth-Hitchcock Medical School. **CME-accredited event, CNE-accredited event**
- Plenary Speaker. At: California DUI Lawyers Association 2014 Conference: DUI-D and DRE, Fresno, CA. **MCLE-accredited event**
- Oral and Written Testimony before the Nevada Advisory Commission of the Administration of Justice's Subcommittee on Medical Use of Marijuana, Las Vegas, NV: August 21, 2014
- Faculty member and plenary speaker. At: Eighth National Clinical Conference on Cannabis Therapeutics, Portland, OR, 2014. Sponsored by Patients Out of Time and the University of California at San Francisco School of Medicine. **CME-accredited event**
- Plenary Speaker. At: Eighth National Clinical Conference on Cannabis Therapeutics, Pre-Conference Workshop, Portland, OR, 2014. **CLE-accredited event**
- Plenary Speaker. At: California DUI Lawyers Association 2014 Conference: DUI Drugs in the State Capitol, Sacramento, CA. **CLE-accredited event**
- Plenary Speaker. "Equating Cannabinoid Concentrations With Psychomotor Impairment: Limitations and Concerns." At: DUI Drug Cases & DRE: Mastering

the Science & Trial Skills, Denver, CO, 2013. Sponsored by International Legal & Forensic Science Services

- Plenary Speaker. At: Colorado Criminal Defense Bar 2013 DUI Conference, Breckenridge, CO, 2013. Sponsored by the Colorado Criminal Defense Bar
- Oral Testimony before the Washington state House of Representatives, House Committee on Public Safety, Olympia, Washington: February 6, 2013.
- Plenary Speaker. At: California Association of Toxicologists Spring 2012 Meeting, San Jose, 2012. Sponsored by the California Association of Toxicologists
- Plenary Speaker. At: Oregon Criminal Defense Lawyers Association 2012 DUI Defense Conference. Silverton, OR.
- Plenary Speaker. At: Café Conversation. Sponsored by the Chabot Space and Science Center. Oakland, CA.
- Plenary Speaker. At: DUID Marijuana Per se Working Group/Drug Policy Task Force, Denver, CO, 2011. Sponsored by the Colorado Commission on Criminal and Juvenile Justice
- Plenary Speaker. At: 40th Annual Convention of the National Association of School Psychologists, New Orleans, LA, 2008.
- Plenary Speaker. At: Fifth National Clinical Conference on Cannabis Therapeutics, Pacific Grove, CA, 2008. Sponsored by Patients Out of Time and the University of California at San Francisco School of Medicine. **CME-accredited event**

Training Seminars:

- Special Session: Driving Under the Influence of Drugs. Washington, DC, 2008. Sponsored by: American Academy of Forensic Sciences (AAFS).
- 34th Annual Meeting of the Society of Forensic Toxicologists. Nashville, TN, 2005. Sponsored by SOFT.
- Developing Global Strategies for Identifying, Prosecuting, and Treating Drug-Impaired Drivers, Tampa, FL, 2004. Sponsored by: The Counterdrug Technology Assessment Center (CTAC) at the Office of National Drug Control Policy; Cosponsored by: The International Association of Forensic Toxicologists (TIAFT), the International Council on Alcohol, Drugs, and Traffic Safety (ICADTS), and the National Institute on Drug Abuse (NIDA).

Education

- Bachelor of Arts, Political Science
Saint Bonaventure University, 1994
Graduated *cum laude*

Additional Qualifications

- Mr. Armentano has reviewed, summarized, and commented upon over 30,000 scientific studies and pertinent to cannabis use, its pharmacokinetics, and its impact on behavior.
- Mr. Armentano has presented oral and/or written testimony on cannabis policies before various state legislatures and also federal agencies.
- Mr. Armentano is a nationally and internationally recognized expert on the subject of cannabis, the law, the plant's health implications, and public policy. His writing has appeared in well over 1,500 publications, including *The New York Times*, *The Los Angeles Times*, and *Congressional Quarterly*, *Cato Unbound*, as well as in various scholarly journals. He has appeared in interviews for hundreds of national and international media outlets, including CNN, the BBC, Fox News, and Al Jazeera.
- Mr. Armentano is one of the most quoted experts in the national media on cannabis and public policy, having been quoted as an authority in thousands of media in forums such as *The New York Times*, *The Los Angeles Times*, *Scientific American*, *C-Span*, *CNN*, *Congressional Quarterly*, and *National Public Radio*.
- Mr. Armentano is the primary content provider for the NORML.org website, one of the most trafficked marijuana content sites in the United States.
- Mr. Armentano formerly provided online content to TheAnswerPage.com, an online medical educational resource that provides daily education to healthcare professionals in 120 countries, as well as CME credit. A version of this content is required curriculum for physicians in participating in several state medical cannabis programs.
- For over a decade, Mr. Armentano served on the faculty of Oaksterdam University in Oakland, CA, where he instructed thousands of graduates about issues pertaining to cannabis science and health effects. He also served as Chair of the Science Department and was involved in creating curriculum for the school.

- Mr. Armentano was a collaborator for the development of the ‘My Canary’ iPhone application, which allowed subjects to measure their psychomotor and cognitive performance following cannabis ingestion. The app was highlighted by *Fast Company*, *CNN*, *The Daily Mail*, *BusinessInsider.com*, and the *International Business Times*, among others.
- Mr. Armentano served as a consultant to the Canadian Public Health Association’s “Pot and Driving” campaign, a project to increase awareness among young Canadians age 14 to 18 about the risks of cannabis-impaired driving.
- Mr. Armentano served as a columnist for High Times Magazine and the *High Times* website from 1995 to 2018, penning hundreds of articles and features.
- Mr. Armentano is a contributing columnist to TheHill.com, an inside-the-Beltway publication and website that is read by the White House and by more members of Congress than any other news and commentary site.
- Mr. Armentano has offered legal consultation in dozens of criminal and civil cases involving issues pertaining to the science of cannabis and/or cannabis policy.

Exhibit B



The National Organization for the Reform of Marijuana Laws (NORML) is a political advocacy organization representing the interests of responsible adult cannabis consumers. Founded in 1970, NORML is the oldest cannabis policy reform organization operating in the United States.

Over the past five decades, NORML has been party to numerous cannabis rescheduling petitions.^[1] NORML is providing these comments today in support of the reclassification of botanical cannabis (Docket No. DEA-1362).

NORML shares the view expressed by the Department of Health and Human Services (HHS) that cannabis "has a currently accepted medical use" and that its comparatively low abuse potential is inconsistent with the criteria required for substances in either Schedule I or Schedule II. The HHS appropriately determined that neither scientific evidence nor real-world clinical experience support cannabis' inclusion in either category. Specifically, on page 57 of its review, HHS affirms, "The risks to public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological data," including hospitalizations, unintentional exposures, and overdose deaths.

Cannabis Possesses Accepted Medical Utility

HHS acknowledges that cannabis possesses "accepted medical use" because members of the health and medical community widely accept its legitimate use in the treatment of specific conditions, including pain, and because cannabis can be administered safely under medical supervision. Specifically, on page 24 of its review, HHS acknowledges:

"More than 30,000 health care practitioners are authorized to recommend the use of marijuana for more than six million registered patients, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States. For several jurisdictions, these programs have been in place for several years, and include features that actively monitor medical use and product quality characteristics of marijuana dispensed."

Thirty-eight states, the District of Columbia, Guam, Puerto Rico, the Commonwealth of the Northern Mariana Islands, and the US Virgin Islands have enacted laws providing for patients' access to plant-derived cannabis and medical cannabis products.^[2] Several additional states regulate patients' access to plant-derived low THC/high CBD products.^[3] Many states now require physicians to take Continuing Medical Education training prior to issuing medical cannabis recommendations^[4] and a growing number of colleges and graduate schools are offering degrees and certificates in the field of cannabis medicine.^[5]



No state legislature has ever repealed patients' access to plant-derived medical cannabis products. This is clear evidence that medical cannabis can be regulated safely and effectively, and that its public health benefits far outweigh any costs.

Surveys assessing physicians' attitudes and practices toward the use of cannabis confirm that widespread acceptance of its medical utility exists among health professionals. Specifically, a 2022 national survey of family practice doctors, internists, nurse practitioners, and oncologists – co-authored by representatives of the US Centers for Disease Control and Prevention – concluded, "Over two-thirds (68.9%) of clinicians surveyed believe that cannabis has medicinal uses and just over a quarter (26.6%) had ever recommended cannabis to a patient."^[6] A 2022 survey of members of the American Organization for Nursing Leadership similarly determined, "Nurse leaders overwhelmingly supported patients' use of medical cannabis."^[7] Numerous other surveys of health care professionals have yielded similar results.^[8]

Moreover, several notable medical societies and associations – such as the American Nurses Association and the American Public Health Association – are on record urging the federal government to "move expeditiously to make cannabis available as a legal medicine."^[9] A list of these organizations and their endorsements is available on NORML's website at:

<https://norml.org/marijuana/library/health-organizations-endorsements/>

Clinical findings provide the basis for this widespread acceptance among practicing physicians and healthcare professionals. Specifically, a review summarizing the findings of several FDA-approved, randomized placebo-controlled trials assessing the safety and efficacy of botanical cannabis in various patient populations concludes, "Based on evidence currently available the Schedule I classification is not tenable; it is not accurate that cannabis has no medical value, or that information on safety is lacking."^[10]

This conclusion was affirmed by an exhaustive literature review by the National Academy of Sciences, Engineering, and Medicine's Committee on the Health Effects of Marijuana, which found "conclusive or substantial evidence" that cannabis and its active constituents benefit specific patients, including those suffering from chronic pain, nausea, and spasticity.^[11]

Moreover, a recent review of the literature compiled by NORML highlights over 400 peer-reviewed papers documenting the efficacy of either cannabis or its constituents in more than 20 distinct patient populations. Summaries of these studies and links to the studies' abstracts are available on NORML's website at:

<https://norml.org/marijuana/library/recent-medical-marijuana-research/>



Cannabis Possesses an Acceptable Safety Profile Compared to Other Controlled Substances

The authors of the HHS review also conclude that cannabis possesses a superior safety profile as compared to many other controlled substances. Specifically, HHS finds that cannabis is associated with fewer adverse consequences than other Schedule I and Schedule II substances, such as heroin and cocaine (page 45). Notably, HHS further finds that cannabis poses fewer risks to public health than either benzodiazepines (page 57) – a Schedule IV substance – or alcohol (page 45), which is unscheduled.

Other experts have reached similar conclusions. Specifically, a study published in *The Lancet* assessed the harmful effects of various controlled substances on the public and the individual consumer. The study's authors concluded, "Overall, alcohol was the most harmful drug, with heroin and crack cocaine in second and third places."^[12]

Another review, published in the journal *Current Opinion in Pharmacology*, similarly determined that cannabis use, even long-term, possesses a superior safety profile compared to other psychoactive substances. It concluded, "Overall, by comparison with other drugs used mainly for 'recreational' purposes, cannabis could be rated to be a relatively safe drug."^[13]

Most recently, investigators writing in the journal *Frontiers in Psychiatry* assessed the safety risks associated with the use of cannabis. They concluded that its risk of dependence and abuse potential are "substantially lower than those posed by many illegal and legal substances, including tobacco and alcohol."^[14]

This conclusion is hardly surprising. Consumers' use of alcohol and tobacco are among the leading causes of preventable deaths in America. According to the American Lung Association, "Smoking [tobacco] is the number one preventable cause of death in the United States, killing over 480,000 people per year."^[15] Alcohol abuse is estimated to contribute to more than 178,000 US deaths annually, making it "one of the leading preventable causes of death in the United States."^[16] By contrast, several longitudinal studies have failed to link cannabis use to an increased risk of premature death^[17] – including deaths due to lung^[18] and other tobacco-related cancers^[19] after researchers adjusted for potential confounders.

It is well established that alcohol – when consumed to excess in a short period of time – can cause lethal overdose. Several thousand Americans die each year because of alcohol poisoning.^[20] Alcohol is also a contributing factor to more than 1 in 6 opioid overdose deaths, according to the National Institute on Alcohol Abuse and Alcoholism.^[21] By contrast, THC – the primary psychoactive ingredient in cannabis – cannot cause lethal overdose, regardless of the quantity ingested. Specifically, data published in *The American Scientist* reported that the "ratio



of fatal dose to effective dose" is 10 to 1 for alcohol, but that no ratio could be calculated for cannabis.^[22] Further, the US Drug Enforcement Administration's own literature acknowledges, "No deaths from overdose of marijuana have been reported."^[23]

The determination by HHS that cannabis use does not possess the same public health burden as does the use of alcohol (unscheduled), tobacco (unscheduled) or other controlled substances currently regulated in lower schedules of the CSA (e.g., benzodiazepines) is consistent with decades of worldwide scientific literature. While HHS ultimately recommends transferring cannabis from Schedule I to Schedule III, NORML wishes to emphasize that these findings similarly provide a factual basis for removing cannabis from the CSA entirely. Although the HHS is not recommending descheduling at this time, NORML asserts that this position is the most appropriate one and that descheduling cannabis should be adopted by future administrations.

Responding to Critics' Concerns: Cannabis and ER Visits

While some opponents of reclassification highlight that cannabis exposure may, in some rare instances, lead to ER visits, it must be emphasized that these situations are typically due to either inadvertent exposure or overconsumption. However, even in these 'worst-case' scenarios – such as the accidental ingestion of a THC-infused edible product by a young child – ER treatment typically consists of no more than the administration of "intravenous fluids and benzodiazepines" prior to the patient's discharge.^[24] No deaths due to cannabis ingestion have ever been reported.

Responding to Critics' Concerns: Cannabis and Driving Performance

While acute cannabis intoxication can influence certain psychomotor skills, it is a far less significant contributor to motor vehicle accidents than most other controlled substances, particularly alcohol. Specifically, a prospective case-control study by the National Highway Traffic Safety Administration determined that THC-positive drivers possess virtually no greater risk of being involved in a motor vehicle crash (Odds Ratio 1.05) than drug-free drivers after researchers controlled for confounders (age and gender). By contrast, drivers in the same study with a blood alcohol level of 0.08 possessed a nearly four-fold crash risk (Odds Ratio 3.93) compared to drug-free drivers, even after researchers controlled for the same confounders.^[25] This conclusion is consistent with those of other studies finding that drivers who test positive for the presence of THC alone possess low^[26] to no^[27] motor vehicle crash risk, whereas alcohol-positive drivers possess a nearly six-fold risk of accident.^[28]



This contrast is likely because subjects under the influence of THC typically engage in compensatory driving behaviors,^[29] – including reducing their mean speed^[30] and leaving greater headway between themselves and the cars in front of them.^[31] In contrast, drivers under the influence of alcohol often drive in a more reckless manner and engage in more risk-taking behaviors. Emergency department data finds^[32] that those who test positive for alcohol are far more likely to be in a motor vehicle accident requiring emergency care than are those who test positive for cannabis.^[33]

While some have expressed concern that liberalizing cannabis' legal status may inadvertently reduce social stigmas discouraging driving while under the influence of cannabis, several studies indicate that the opposite is true. For instance, a 2024 study published in the journal *Public Health* observed a "decrease in driving under the influence of marijuana in states with legalized medical marijuana relative to those states where it remained illegal."^[34] Similarly, a 2022 study reported, "The risk of self-reported DUIC [driving under the influence of cannabis] was lower in recreational and medical cannabis states compared to states without legal cannabis."^[35] A 2021 study reported that adults residing in states where cannabis is legal are less tolerant of drugged driving behavior than are their counterparts in jurisdictions where cannabis remains prohibited.^[36]

Responding to Critics' Concerns: Cannabis-Induced Psychosis

Though anecdotal claims of rising rates of cannabis-induced psychosis persist, thus far these claims have not been substantiated by available data. Specifically, authors of a recently published meta-analysis in the journal *Nature: Mental Health* assessed the relationship between cannabis use and the onset of cannabis-associated psychotic symptoms (CAPS) in 162 studies involving over 210,000 subjects. They reported that the percentage of cannabis consumers who ever experience acute psychosis is low (approximately one-half of one percent), but that those with pre-existing mental health and personality disorders, such as bipolar disorder, may be at greater risk. They also dismissed concerns that the use of higher-potency THC products increases one's risk of psychosis, finding, "[N]either young age of onset of cannabis use nor high-frequency use of cannabis or the preferred type of cannabis (strains high in THC, strains high in CBD) was associated with CAPS."^[37]

A 2022 study involving over 233,000 lifetime cannabis consumers yielded similar findings. Scientists reported that those with a prior diagnosis of psychosis were 14 times more likely to suffer from cannabis-induced psychotic symptoms as compared to those without a prior mental health diagnosis. Overall, the study's authors concluded, "Rates of CAPS as observed here are comparable to rates of other drug-induced psychosis, such as alcohol-associated psychosis (around 0.4 – 0.7 percent)."^[38]



Longitudinal data of adult twins provides compelling evidence that the cumulative use of cannabis is not associated with an increased risk of psychoticism in those who do not have a preexisting psychiatric disorder. Writing in 2024 in the *Journal of Psychopathology and Clinical Science*, scientists concluded: "Lifetime exposure to cannabis has few persistent effects on mental health and other psychosocial outcomes. ... Cannabis consumption did not predict within-pair differences in psychoticism."^[39]

Notably, jurisdictions that have legalized the adult use of cannabis have not experienced increases in cannabis-induced psychosis or other adverse psychiatric events at the population level. For example, a pair of Canadian studies found no rise in hospitalizations due to cannabis-induced psychosis^[40] or schizophrenia^[41] in the years following legalization.

Similarly, the adoption of state-level legalization laws in the United States is not correlated with an uptick in psychosis-related health outcomes. Specifically, a 2022 paper published in the *Journal of the American Medical Association (JAMA) Network Open* found no association between cannabis legalization and overall rates of psychosis-related diagnoses or prescribed antipsychotics. Its authors concluded:

"This study is the first and largest, to our knowledge, to quantify the association of medical and recreational cannabis policies with rates of psychosis-related health care claims across US states. ... [W]e did not observe a statistically significant association of state cannabis policy level with overall rates of psychosis-related diagnoses or prescribed antipsychotics. ... As US states continue to legalize the use, production, promotion, or sale of cannabis, continued examination of the implications of state cannabis policies for psychotic disorders may be informative, particularly with study designs that yield precise estimates in high-risk population subgroups."^[42]

Responding to Critics' Concerns: Do Higher-THC Products Pose Unique Risks to Health?

Higher-potency THC products, like hashish, are not a new phenomenon and opponents of cannabis reform policies have long tried to stigmatize these higher-potency products as uniquely dangerous.^[43] However, data fails to substantiate these claims.

Notably, patients enrolled in federally regulated medical cannabis access programs in Canada, Israel, and Europe typically consume cannabis products containing at least 20 percent THC. These patients seldom report adverse side-effects.^[44]



Since 1985, patients in the United States have been able to access the FDA-approved drug dronabinol, which consists solely of synthetic THC in sesame seed oil. In 1999, the Drug Enforcement Administration downgraded dronabinol from Schedule II to Schedule III^[45] because it lacks a high abuse potential. Data compiled in 2023 finds that fewer than three percent of patients prescribed dronabinol suffer adverse reactions from the drug. These side effects most typically include "abdominal pain, euphoria, and dizziness."^[46]

In state-legal markets, most consumers do not gravitate toward high-THC products. According to state sales data, consumers most frequently purchase lower-potency cannabis flower over higher-potency concentrates.^[47] When consumers do encounter high-THC products, they "simply use less of [it] to achieve the same levels of intoxication."^[48]

Responding to Critics' Concerns: Cannabis and IQ

Allegations that cannabis use decreases intelligence quotient are primarily based upon the findings of a single longitudinal study. The paper, published by Madeline Meier and a team of Duke University researchers in 2012, reported that the onset of cannabis use in early adolescence is associated with an average decline of eight IQ points by middle-age.^[49]

However, a critique of Meier's study published shortly thereafter in the same journal countered that the reported changes in IQ were consistent with socioeconomic differences among the study's participants and that the "true effect [of cannabis exposure] could be zero."^[50]

In the following years, better controlled longitudinal studies have consistently failed to replicate Meier's findings. For example, a British study of more than 2,000 teens determined that cannabis exposure prior to age 15 "did not predict either lower teenage IQ scores or poorer educational performance ... once adjustment is made for potential confounds."^[51]

Researchers at the University of Southern California and at the University of Minnesota similarly assessed the potential relationship between cannabis and IQ in two longitudinal investigations of adolescent twins. They concluded:

"We find little evidence to suggest that adolescent marijuana use has a direct effect on intellectual decline.... The lack of a dose-response relationship, and an absence of meaningful differences between discordant siblings lead us to conclude that the deficits observed in marijuana users are attributable to confounding factors that influence both substance initiation and IQ rather than a neurotoxic effect of marijuana."^[52]



Notably, even Meier acknowledged this lack of correlation in her later work. Writing in 2018 in the journal *Addiction*, she and her colleagues acknowledged: "Short-term cannabis use in adolescence does not appear to cause IQ decline or impair executive functions, even when cannabis use reaches the level of dependence. Family background factors explain why adolescent cannabis users perform worse on IQ and executive function tests."^[53]

Conclusion

The available data clearly shows that cannabis does not meet the necessary criteria of either a Schedule I or Schedule II controlled substance. While NORML strongly believes cannabis should be removed from the CSA altogether^[54] – thereby harmonizing federal cannabis policy with those of most US states – we do not dispute the factual basis underlying HHS' recommendation to move botanical cannabis to Schedule III or lower. It would be arbitrary and capricious for the DEA to reject HHS' findings of fact and maintain existing prohibitions of the cannabis plant.

^[1] NORML online factsheet. A brief history of cannabis rescheduling petitions in the United States.

<https://norml.org/marijuana/fact-sheets/a-brief-history-of-cannabis-rescheduling-petitions-in-the-united-states/>

^[2] NORML summary of states/territories with medical marijuana laws.<https://norml.org/laws/medical-laws/>

^[3] Ibid.

^[4] Federation of State Medical Boards. CME Requirements for Medical Marijuana: State-by-State Overview.

<https://www.fsmb.org/siteassets/advocacy/key-issues/medical-marijuana-cme-requirements.pdf>

^[5] American Journal of Endocannabinoid Medicine. *Cannabis education: US sees influx of college and grad level cannabis medicine programs*. October 3, 2023.

<https://www.endocannabinoidmedicine.com/news/cannabis-education-us-sees-influx-of-college-and-graduate-level-cannabis-medicine-programs/>

^[6] Schauer et al., 2022. *Clinician beliefs and practices related to cannabis*. Cannabis and Cannabinoid Research.

<https://www.liebertpub.com/doi/10.1089/can.2020.0165>

^[7] Kurtzman et al., 2022. 'We want what's best for patients.' Nurse leaders' attitudes about medical cannabis: A qualitative study. *International Journal of Nursing Study Advances*.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11080284/>

^[8] For additional examples, see NORML's online factsheet: Health Clinicians' Attitudes Toward Cannabis.

<https://norml.org/health-clinicians-attitudes-toward-cannabis/>

^[9] APHA Resolution #9513: "Access to Therapeutic Marijuana/Cannabis."

^[10] Grant et al., 2012. *Medical marijuana: Clearing away the smoke*. *Open Journal of Neurology*.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358713/>

^[11] National Academy of Sciences. 2017. The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. Page 127. <https://nap.nationalacademies.org/read/24625/chapter/6>

^[12] Nutt et al. 2010. *Drug harms in the UK: A multicriteria decision analysis*. *The Lancet*.

<https://pubmed.ncbi.nlm.nih.gov/21036393/>

^[13] Iverson. 2005. *Long-term exposure to cannabis*. *Current Opinion in Pharmacology*.

<https://pubmed.ncbi.nlm.nih.gov/15661628/>



^[14] Heal et al., 2024. *A critical assessment of the abuse, dependence, and associated safety risks of naturally occurring and synthetic cannabinoids*. *Frontiers in Psychiatry*. <https://pubmed.ncbi.nlm.nih.gov/38915848/>

^[15] American Lung Association online factsheet: Tobacco Facts. <https://www.lung.org/research/sotc/facts>

^[16] National Institutes of Health. NIAAA factsheet: Alcohol-Related Emergencies and Deaths in the United States, 2024.

<https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics/alcohol-related-emergencies-and-deaths-united-states>

^[17] See, for instance: Andreasson and Alleback. 1990. *Cannabis and mortality among young men*. *Scandinavian Journal of Social Medicine*. <https://pubmed.ncbi.nlm.nih.gov/2320981/> "After controlling for social background variables in a multivariate model, no excess mortality was found." | Sidney et al. 1997. *Marijuana use and mortality*. *American Journal of Public Health*. <https://pubmed.ncbi.nlm.nih.gov/9146436/> "Marijuana use in a prepaid health care-based study cohort had little effect on non-AIDS mortality in men and on total mortality in women." | Manrique-Garcia et al. 2016. *Cannabis, psychosis, and mortality: A cohort study of 50,373 Swedish men*. *American Journal of Psychiatry* <https://pubmed.ncbi.nlm.nih.gov/27102239/> "The authors found an excess mortality among subjects with psychotic disorders, but the level [of excess mortality] did not differ between those with a history of cannabis use and those without such a history."

^[18] Tashkin and Tan. 2022. *Inhaled marijuana and the lung*. *The Journal of Allergy and Clinical Immunology*. [https://www.jaci-inpractice.org/article/S2213-2198\(22\)00495-0/abstract](https://www.jaci-inpractice.org/article/S2213-2198(22)00495-0/abstract) "On balance, the available evidence at least thus far does not suggest that marijuana smoking poses an increased risk of lung cancer when adjustments are made for concomitant tobacco smoking."

^[19] Sidney et al. 1997. *Marijuana use and cancer incidence*. *Cancer Causes & Controls*.

<https://pubmed.ncbi.nlm.nih.gov/9328194/> "Marijuana use also was not associated with tobacco-related cancers or with cancer of the following sites: colorectal, lung, melanoma, prostate, breast, cervix."

^[20] Centers for Disease Control. Deaths from Excessive Alcohol Use – United States, 2016-2021, February 29, 2024. <https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a1.htm>

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<https://www.americanscientist.org/article/the-toxicity-of-recreational-drugs>

^[23] US Drug Enforcement Administration. Marijuana/Cannabis factsheet. <https://www.dea.gov/factsheets/marijuana>

^[24] Cao et al., 2016. *Characterization of edible marijuana product exposures reported to United States poison centers*. *Clinical Toxicology* <https://pubmed.ncbi.nlm.nih.gov/27418198/>

^[25] Compton and Berning. *Drug and Alcohol Crash Risk*. US Department of Transportation Traffic Safety Facts: Research Note, 2015. <https://rosap.nhtl.bts.gov/view/dot/1993>

^[26] Rogeberg. 2019. *A meta-analysis of the crash risk of cannabis-positive drivers in culpability studies: Avoiding interpretational bias*. *Accident Analysis and Prevention*. <https://pubmed.ncbi.nlm.nih.gov/30468948/> "Culpability ORs exaggerate risk increases and parameter uncertainty when misinterpreted as total crash ORs. The increased crash risk associated with THC-positive drivers in culpability studies is low."

^[27] Brubacher et al. 2019. *Cannabis use as a risk factor for causing motor vehicle crashes: A prospective study*. *Addiction*. <https://pubmed.ncbi.nlm.nih.gov/31106494/> "In this multi-site observational study of non-fatally injured drivers we found no increase in crash risk, after adjustment for age, sex and use of other impairing substances, in drivers with THC < 5 ng/ml. For drivers with THC ≥ 5 ng/ml there may be an increased risk of crash responsibility (OR = 1.74), but this result was statistically non-significant and further study is required."



[28] Ibid. See also: Li et al. 2017. *Role of alcohol and marijuana use in the initiation of fatal two vehicle crashes*. Annals of Epidemiology. <https://www.sciencedirect.com/science/article/abs/pii/S1047279716304380> "The adjusted odds ratios of fatal crash initiation were 5.37 for those testing positive for alcohol and negative for marijuana, 1.62 for those testing positive for marijuana and negative for alcohol."

[29] Ronen et al. 2007. *Effects of THC on driving performance, physiological state and subjective feelings relative to alcohol*. Accident Analysis and Prevention. <https://pubmed.ncbi.nlm.nih.gov/18460360/>

[30] Zhao et al. 2024. *The effect of cannabis edibles on driving and blood THC*. Journal of Cannabis Research. <https://pubmed.ncbi.nlm.nih.gov/38822413/>

[31] Sewell et al. 2009. *The effect of cannabis compared with alcohol on driving*. American Journal on Addictions <https://pubmed.ncbi.nlm.nih.gov/19340636/>

[32] Brubacher et al. 2023. *A comparison of cannabis and alcohol use in drivers presenting to hospital after a vehicular collision*. Addiction. <https://pubmed.ncbi.nlm.nih.gov/36898848/>

[33] Choo et al. 2024. *Risk of motor vehicle collision associated with cannabis and alcohol use among patients presenting for emergency care*. Accident, Analysis and Prevention. <https://pubmed.ncbi.nlm.nih.gov/38277855/> "Cannabis alone was not associated with higher odds of MVC [motor vehicle accident], while acute alcohol use alone ... [was] independently associated with higher odds of MVC."

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[35] Dutra et al., 2022. *Cannabis legalization and driving under the influence of cannabis in a national US sample*. Preventive Medicine Reports. <https://www.sciencedirect.com/science/article/pii/S2211335522001061>

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[38] Schoeler et al., 2022. *Rates and correlates of cannabis-associated psychotic symptoms in over 230,000 people who use cannabis*. Translational Psychiatry. <https://www.nature.com/articles/s41398-022-02112-8>

[39] Zellers et al., 2024. *Limited psychological and social effects of lifetime cannabis use frequency: Evidence from a 30-year community study of 4,078 twins*. Journal of Psychopathology and Clinical Science. <https://psycnet.apa.org/record/2024-40025-005>

[40] L'Heureux et al., 2024. *Effect of cannabis legalization in Canada on the incidence of psychosis consultations in Quebec City's psychiatric emergency services*. The Canadian Journal of Psychiatry. <https://journals.sagepub.com/doi/10.1177/07067437241232901> "[There was] 'no increase in the proportion of ED consultations for a psychotic episode in which evidence for cannabis consumption was obtained before and after legalization.'"

[41] Anderson et al., 2022. *Impact of non-medical cannabis legalization with market restrictions on health service use and incident cases of psychotic disorder in Ontario, Canada*. International Journal of Drug Policy. <https://www.sciencedirect.com/science/article/abs/pii/S0955395923003328?via%3Dihub> "[The] implementation of Canada's cannabis legalization framework was not associated with evidence of significant changes in cannabis-induced psychosis or schizophrenia ED [emergency department] presentations."

[42] Elser et al., 2023. *State cannabis legalization and psychosis-related health care utilization*. JAMA Open Network. <https://pubmed.ncbi.nlm.nih.gov/36696111/>

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- ^[46] O'Donnell et al., 2023. Dronabinol. <https://www.ncbi.nlm.nih.gov/books/NBK557531/>
- ^[47] MJBizDaily. *Flower still No. 1 with consumers, even as innovative product types crowd store shelves*. November 1, 2022. <https://mjbizdaily.com/flower-no-1-with-consumers-amid-innovative-product-types/>
- ^[48] Cuttler et al., 2021. *Acute effects of high-potency cannabis flower and cannabis concentrates on everyday life memory and decision making*. Nature: Scientific Reports. <https://www.nature.com/articles/s41598-021-93198-5>
- ^[49] Meier et al., 2012. *Persistent cannabis users show neuropsychological decline from childhood to midlife*. Proceedings of the National Academy of Sciences. <https://pubmed.ncbi.nlm.nih.gov/22927402/>
- ^[50] Ole Rogeberg. 2013. *Correlations between cannabis use and IQ change in the Dunedin cohort are consistent with confounding from socioeconomic status*. Proceedings of the National Academy of Sciences. <https://www.pnas.org/doi/10.1073/pnas.1215678110>
- ^[51] Mokrysz et al. 2016. *Are IQ and educational outcomes in teenagers related to their cannabis use? A prospective cohort study*. Journal of Psychopharmacology. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4724860/>
- ^[52] Jackson et al., 2015. *Impact of adolescent marijuana use on intelligence: results from two longitudinal twin studies*. Proceedings of the National Academy of Sciences. <https://www.pnas.org/doi/10.1073/pnas.1516648113>
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- ^[54] NORML. *Cannabis must be removed from the Controlled Substances Act to resolve state/federal conflicts*. June 23, 2023. <https://norml.org/blog/2023/06/23/norml-op-ed-cannabis-must-be-removed-from-the-controlled-substances-act-to-resolve-state-federal-conflicts/>

Exhibit C

Biography for Beau Whitney, Whitney Economics

Beau Whitney, Cannabis Economics, Operations and Supply Chain Expert

Beau Whitney is the founder and Chief Economist at Whitney Economics, a global leader in cannabis and hemp business consulting, data, and economic research. Whitney Economics is based in Portland, Oregon.

Serving an international clientele, Beau is considered one of the leading cannabis economists in the U.S. and globally. His applications of economic principles to create actionable operational and policy recommendations has been recognized by governments, and throughout the economic, investment, business communities. In 2022, Beau presented data and insights about cannabis and hemp economics at the United Nations.

His white papers analyzing the adult-use, medical and industrial cannabis markets have been referenced in the Wall Street Journal, Washington Post, New York Times, USA Today, the Associated Press, as well as in leading cannabis industry publications.

Beau Whitney is a member of the American Economic Association, the Oregon chapter president of the National Association for Business Economics, is a member of multiple regulatory advisory committees throughout the U.S. and participates on the Oregon Governor's Council of Economic Advisors.

Beau has provided policy recommendations at the state, national and international levels and is considered an authority on cannabis economics and the supply chain. Whitney Economics does not take a position on the legality of cannabis or on pending legislation.

Beau R. Whitney

3211 SW Luradel St, Portland, OR 97219, 503-724-3084

WhitneyEconomics@gmail.com**QUALIFICATIONS SUMMARY**

I am a business operations and governmental affairs specialist with 20 years of progressively increasing scope and responsibilities. I am also a professor of economics and business management. With this combination, I can blend together the theoretical elements of business management and apply them to real life business applications. I have a keen ability to make tactical decisions to set and support strategic direction. I can also condense large amounts of information into concise, data driven presentations and help direct an organization by establishing a clear set of business objectives. The bottom line is that I get results.

The combination of business operations skills, economic analysis and cannabis industry experience is unique in the cannabis market, and has set me apart as a leading cannabis economist globally. I have collaborated on two books in 2017 and published whitepapers on a wide-ranging set of topics including analysis of federal and state cannabis tax policies, consumer pricing sensitivity, the effect of tax policy on the illicit market, how economics can help shape cannabis public policy, the strengths and weaknesses of a state and federal cannabis legislation, and an Oregon cannabis jobs report. I have also developed demand models for the entire US cannabis market and contributed my insights to the State of Oregon Office of Economic Analysis.

History of excellence in ...

- | | | |
|----------------------------|--------------------------|----------------------------|
| • Business Operations | • Strategic Planning | • Tactical Decision Making |
| • Forecasting and Modeling | • S&OP | • Economic Analysis |
| • Compliance | • Executive Management | • Governmental Affairs |
| • Policy Analysis | • Training and Mentoring | • Public Speaking |

PROFESSIONAL EXPERIENCE**Whitney Economics, LLC, Portland, Oregon****2014 - Present**

Economic Business Advisor

The primary objective of this role is to provide economic and management consulting services to small businesses in emerging industries that will allow them to scale their business for rapid growth

- Contributor to the Oregon Office of Economic Analysis cannabis tax revenue forecast
- Participant in the Oregon Governor's Council of Economic Advisor meetings
- Provided cannabis regulatory and market reports for governments in U.S., Mexico, Zimbabwe, Lebanon, Afghanistan, Ireland, Romania, Slovenia
- Publish regular economic updates that include macro and regional updates as well as an industry specific summary
- Considered an expert on hemp economics
- Provided reports to state regulators to help right size regulatory programs and license issuance
- Board member of multiple cannabis and hemp companies in U.S. and Canada
- Create strategic, marketing and business plans for small businesses
- Conduct regular audits of strategic plans and present recommendations on how to adjust corporate strategy
- Perform regular reviews of business plans to help companies identify risks and course corrections needed to address emerging threats to their business strategies
- Provided expert testimony in cannabis trials
- Provide additional finance, marketing, supply chain and business services as needed

New Frontier Data, Inc. Portland, Oregon**2017 - 2020**

Vice President and Senior Economist

The primary objective of this role is to provide research, economic modelling and analysis in the cannabis market for the leading cannabis big data companies in the United States

- Provide research and analysis to individual clients, as well as state and federal officials
- Write and edit papers on topics including taxation, supply chain, economic impacts, regulatory and governmental policy and the global cannabis market
- Support speaking engagements and represent New Frontier Data at conferences. Gave in excess of 30 speeches in 2018 and was interviewed live on Bloomberg television.
- Collaborated on 2017 publication of the “Cannabis Industry Annual Report”

University of Phoenix, Tigard, Oregon**2013 - 2018**

Associate Faculty (Adjunct Professor)

Ground based instructor bringing innovative learning techniques to University setting (Part time/evenings)

- Content expert in Economics, Management and Strategy
- 360 hours of classroom teaching experience since 2013, including 18 courses

Golden Leaf Holdings (F.M.A. Golden XTRX), Portland, Oregon**2014 - 2016**

Vice President of Regulatory and Governmental Affairs, Chief Economist, Chief Operations Officer

The primary objective of this role is to manage all regulatory compliance issues associated with a vertically integrated medical and recreational marijuana company and serve as the governmental liaison at the local, state and national levels

Vice President of Regulatory and Governmental Affairs (10/15 – 12/16)

- Implemented Governmental Affairs strategies and Regulatory Compliance Programs
- Published Oregon Cannabis Economic forecast, tax policy recommendations based on elasticity of demand, and multiple economic impact analysis of legislative and regulatory policies
- Supported audit and other activities to prepare for public stock offering, including investor site visits, regulator reviews, banker inspections and recruited business partners
- Keynote speaker at Harvard Business School panel, Cannabis World Congress and at Oregon Creative Cannabis Conference

Chief Operating Officer (10/14 – 10/15)

- Responsible for regulatory compliance, grow operations, oil extraction and production, inventory control, dispensary operations, edibles, patient management, security and governmental affairs
- Increased valuation from \$10M to \$60M while serving as COO, prior to public offering
- Increased capacity at the production level by 100% that increased revenues in excess of \$1M/month
- Successfully completed dispensary build out and restoration of retail operations
- Managed a team of 35 full time employees

Traeger Pellet Grills, Wilsonville, Oregon**2013 - 2014**

Director of Supply Chain

The primary objective of this role was to manage the demand forecasting, finished goods and raw material procurement and inventory control processes in order to maintain maximum customer support at the lowest possible cost. The role of Supply Chain Director was for a distribution company with revenues in excess of \$100M, spends of \$30M - \$40M and with manufacturing facilities in China. I was brought in by ownership to help scale the business during a period of high growth

- Created and facilitated a demand planning (Forecasting) process across multiple functional areas, laying the foundation for the establishment of an S&OP process
- Established robust supply planning process, including a weekly supplier confirmation of supply

- Streamlined cross functional processes to enable scale, transparency and increased communications
- Established a purchasing controls process for spends of \$30M - \$40M annually
- Implemented inventory control, min-max replenishment and tracking processes for over 200 SKUs

TriQuint Semiconductor, Hillsboro, Oregon**2007 - 2013**

Mobile Devices Business Operations Manager

The primary objective of this role was to manage the forecast, supply and inventory control process and provide data in order to make economics decisions regarding capital expenditures, capacity expansion and inventory. This senior analyst role supported the largest division in the corporation with annual revenues in excess of \$500M and used statistical data analysis to model demand, derive appropriate inventory levels and assess risk. Developed, published, and presented regular updates to executive management summarizing the health of the business in preparation for quarterly updates to the Wall Street analysts.

- Managed \$100M inventory mix to achieve best in class inventory valuation and record high delivery performance and revenue maximization
- Increased inventory valuation by 15% to 95%, while maintaining \$20M in buffer inventory
- Coordinated monthly forecast review process which included marketing trend analysis, macro and micro economic summaries and updates on competitive forces
- Identified, developed and implemented process improvement initiatives
- Represented the Mobile business unit on the Sales and Operations Planning (S&OP) team
- Managed small team of analysts

Intel Corporation, Hillsboro, Oregon**2000 - 2007**

Supply Demand Manager / Divisional Planner (2000 – 2005, 2006/07), Commodity Specialist (2005 – 2006)

The primary objective of these roles were to provide analysis on the supply and demand of Intel products and to help facilitate economic decision making by publishing data oriented updates and recommendations. It was through a series of promotions and expanding roles that I was able to manage all aspects within the supply chain. Duties included managing the forecasting process, communicating demand to the factories, managing supply related issues and inventory control. Expanded scope to include negotiating large long termed commodities contracts and publishing a corporate policy document.

- Managed wireless NIC supply and demand issues associated with the launch of the Centrino Mobile Technology platform. Contributed to the publications of weekly reports to executive management
- Presented Operations update at monthly Supply Demand Indicator meetings (SDI) to senior management
- Negotiated multi commodity goods contract (5 year deal with spends in excess of \$200M per year) between Intel and the largest importer and exporter in China
- Supply Demand Manager / Master Scheduler for LAN Access Division: Developed builds plans and interfaced with factories to support the business unit forecast
- Produced corporate strategic policy paper outlining guidelines and criteria for Intel interaction with governments. (Global policy document)

Rivals.com, Seattle, Washington**2000**

Manager of Operations

Reporting to the CFO at a start up dot.com, supported a hybrid role performing typical operations management duties as well as financial analysis of projects and corporate initiatives (NPV/ROI, ASP modeling, contract negotiations)

- Researched and published marketing and business analysis for ASP model for Board of Directors.
- Led negotiations for e-commerce initiative, including financial software selection.
- Successfully implemented CRM software package for 200 users.
- Managed \$6 million construction of new corporate headquarters.

Previous professional roles from 1986 to 1999

- Research Analyst
- Freight Forwarder
- International Export Manager
- International Loan Coordinator
- Investment Analyst for Japanese Investment Company

EDUCATION**Thunderbird School of Global Management****1999**

Master of Business Administration

Concentration: Finance, Operations Management, and International Marketing

*Created business and political risk models***Macalester College, St. Paul, Minnesota****1986**

Bachelor of Arts: Mathematics and Asian Philosophies

*Member of basketball and track teams***SKILLS****Computer:** Word, Excel, Access, PowerPoint, MS Project, Visio, SAP, I2, Microstrategy**Language:** English (Native), Spanish (Proficient), Chinese (Basic / Conversant)**Other:** Member of American Economic Association (AEA)

Member of National Association for Business Economics (NABE Portland Chapter President)

Institute of Business Forecasting (IBF) certificate in Statistical Forecasting

Lived abroad. Visited over 30 countries on 4 continents

RECENT EXPERT TESTIMONY, VALUATIONS, ARBITRATIONS**04/2024: Bar L-3 Ranch, LLC v. Swan Court, LLC d/b/a Patriot Hemp Services, LLC**

Expert in dispute between Hemp cultivator and processor/extractor.

04/2024: Client #7

Expert in case between hemp business owner and law enforcement in Missouri (Currently retained)

12/2023: Client #6Expert in dispute between Board of Directors and claims made by shareholders in multi-state operations.
(Currently retained)**05/2023: Beyerlein v. Barros, et al.**

Lost profits related to a cultivation facility in Oregon

05/2023: Client #5.

Expert report regarding claims made against hemp grower by law enforcement.

08/2022: Hoover Road Real Estate and LivWell Michigan v Defendants: Sy-Bazz Architecture, LLC, BCER Engineering, Inc., Gen-Tech of Colorado LLC, Arizona Generator Technology, Inc., Cultivated Power, Inc., and James G. Kelly.

Lost profits related to a cultivation facility in Michigan

06/2022: Client #4

Lost profits for cultivation facility in Oregon. (Settlement)

07/2020: Client #3

Expert in Hemp trial (currently retained) based in Arizona. Trial was delayed by covid.

09/2019: Aho v JMosh Solution, Clackamas County, Oregon City, OR

Expert lost profits, valuation (Settled before trial)

09/2019: AMG v Bishop, Jackson County, Medford, OR

Expert in Arbitration case (ASP Case number: 180629-3)

12/2018: Clark v Portland Rosin Company, Multnomah County, Portland, OR

Expert, Valuation in Arbitration case (Case number: 19CV16660)

10/2018: Client #2

Valuation of Nevada cannabis retail, California cannabis retail and California cannabis cultivation sites

03/2018: Webb v Mother Earth's Creation, Lane County, Eugene, OR

Expert in Court Trial: Owner / Tenant dispute, Compliance and lost profits (Case number: 17LT07755)

02/2018: State of Oregon v Gabriel Ramirez, Malheur County, Vale, OR

Expert in Court Trial: Inventory / lost profits valuation (Case number: 16CR66896)

09/2017: Client #1

Valuation of Northern California grow operation

06/2017: Owner v Owner, Multnomah County, Portland, OR

Valuation of two retail outlets as part of partnership dissolution

PUBLICATIONS

2024

06/2024: Whitney Economics, Portland, OR

Report: Economic impact analysis of 280E on minority and small businesses **(Draft)**

Analysis provided to White House and OMB (Office of Management and Budget)

05/2024: Whitney Economics, Portland, OR

Report: Massachusetts Licensing Analysis

05/2024: Whitney Economics, Portland, OR

Report: Washington Licensing Analysis

04/2024 Vangst / Whitney Economics, Portland, OR

Report: Vangst U.S. Cannabis Jobs Report

04/2024 Whitney Economics, Portland, OR

Report: Whitney Economics U.S. Cannabis Delinquency Report (2024)

03/2024 Whitney Economics, Portland, OR

White Paper: Summary of Impact of Cannabinoid Bans in Florida (2024)

2023

12/2023 Whitney Economics, Portland, OR

Report: Hemp Derived Cannabinoids in the Hoosier State (2023)

10/2023 Whitney Economics, Portland, OR

Report: U.S. National Cannabinoid report - Whitney Economics (2023)

08/2023 Whitney Economics, Portland, OR

Report: Virginia Hemp Ban: The Economic Impact of SB903 (2023)

07/2023 Whitney Economics, Portland, OR

Report: Texas Cannabinoid Economic Impact Analysis (2023)

06/2023 Whitney Economics, Portland, OR

Report: Whitney Economics – U.S. Cannabis Business Conditions Report (2023)

04/2023 Vangst / Whitney Economics, Portland, OR

Report: Vangst U.S. Cannabis Jobs Report (2023)

03/2023 Whitney Economics, Portland, OR

Report: Florida Cannabinoid Economic Impact Analysis (2023)

03/2023 Whitney Economics, Portland, OR

Report: Virginia Cannabinoid Economic Impact Analysis (2023)

2022

11/2022 Whitney Economics, Portland, OR

Report: Whitney Economics U.S. Cannabis Supply Report (2022)

10/16/2022 Whitney Economics, Portland, OR

White Paper: Michigan Cannabis Supply and Demand Update (at their request, sent to Governor's office and Michigan Cannabis Regulatory Agency)

10/2022 Whitney Economics, Portland, OR

Report: Colorado Cannabinoid Economic Impact Analysis

09/10/2022 Whitney Economics, Portland, OR

White Paper: Cannabis Start-ups Hard Hit by Higher Costs (Published by Leafly)

08/25/2022 Whitney Economics, Portland, OR

White Paper: Cannabis Demand Sees Nominal Impact by Surge in Inflation (Published by Benzinga)

07/05/2022 Whitney Economics, Portland, OR

White Paper: Duped by Big Dope (Published by Benzinga)

04/13/2022 Whitney Economics, Portland, OR

White Paper: New York Requires 425,000 Pounds of Output to Support the Initial Adult-use Ramp (Published by Benzinga)

03/2022 Leafly Whitney Economics, Portland, OR

Report: Leafly Jobs Report 2022

03/15/2022 Whitney Economics, Portland, OR

Report: Whitney Economics U.S. Cannabis Business Conditions Survey Report (Q4 2021)

02/18/2022 Whitney Economics, Portland, OR

White Paper: Whitney Economics on NASS Survey results

2021

11/28/2021 Whitney Economics, Portland, OR

Report: The Economic Impact of Cannabis Legalization in Delaware

10/2021 Leafly / Whitney Economics, Portland, OR

Report: Leafly Cannabis Harvest Report 2021

09/30/2021 Whitney Economics, Portland, OR

White Paper: U.S. Cannabis Operators Facing Downward Pressure on Demand in Q4 (Published by Benzinga)

09/28/2021 Whitney Economics, Portland, OR

Report: The Economic Impact of Cannabis Legalization in Indiana

08/30/2021 Whitney Economics, Portland, OR

White Paper: An Economic Analysis of CAOAs and its Impact on the U.S. Cannabis Industry

03/30/2021 Whitney Economics, Portland, OR

White Paper: Corporate Tax Hikes Forcing A Watershed Moment For Cannabis Policy Reform (published by Benzinga)

03/2021 Leafly / Whitney Economics, Portland, OR

Report: Leafly Jobs Report 2021

01/21/2021 Whitney Economics, Portland, OR

White Paper: Cannabis Retailers Under Duress (Published by Benzinga)

2020

12/2020 Whitney Economics, Portland, OR

Report: Whitney Economics Hemp Cultivation Report 2020 - Full Report

12/2020 Whitney Economics, Portland, OR

Report: WE_ Hawaii Hemp Economic Impact Assessment

08/11/2020 Whitney Economics, Portland, OR

Report: An Analysis of Pomona, California POMONA REGULATE CANNABIS ACT OF 2018

08/01/2020 Whitney Economics, Portland, OR

Report: Interstate Cannabis Commerce and Social Equity Funding

05/28/2020 Mantis Growth Investments / Whitney Economics, Portland OR

Report: WE Cannabis in a Recession

03/2020 Leafly / Whitney Economics, Portland, OR

Report: Leafly Jobs Report 2020

2019

11/20/2019 Whitney Economics, Portland, OR

Report: The Field of Dreams: An Economic Survey of the United States Hemp Cultivation Industry

11/17/2019 New Frontier Data, Washington D.C.

Blog/Question of the Week: Ask our Experts: Price Declines and their Impact on the Market

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-11-17-19-price-declines-and-their-impacts-on-the-market/>

11/05/2019 New Frontier Data, Washington D.C.

Report: The U.S. Cannabis Cultivation Report: 2019 Legal and Illicit Output by State

11/10/2019 New Frontier Data, Washington D.C.

Blog: Amid Raging Wildfires, Is California's Market Up in Smoke?

<https://newfrontierdata.com/marijuana-insights/amid-raging-wildfires-is-californias-market-up-in-smoke/>

11/02/2019 New Frontier Data, Washington D.C.

Blog: Bearing Fruit from U.S. Cultivation Estimates for 2019

<https://newfrontierdata.com/marijuana-insights/bearing-fruit-from-u-s-cultivation-output-estimates-for-2019/>

10/17/2019 New Frontier Data, Washington D.C.

Report: The Canada Cannabis Report: 2019 Industry Outlook

(Co-Author)

10/13/2019 New Frontier Data, Washington D.C.

Blog/Question of the Week: Ask our Experts: Industry Revenues After Federal Legalization

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-industry-revenues-after-federal-legalization/>

10/06/2019 New Frontier Data, Washington D.C.

Blog: The Business of Cannabis: U.S. Federal Legalization Could Translate to \$128.8 Billion in Taxes and 1.6 Million Jobs

<https://newfrontierdata.com/marijuana-insights/the-business-of-cannabis-u-s-federal-legalization-could-translate-to-128-8-billion-in-taxes-and-1-6-million-jobs/>

10/01/2019 New Frontier Data, Washington D.C.

Report: Cannabis in the U.S. Economy 2019: Jobs, Growth and Tax Revenue

09/29/2019 New Frontier Data, Washington D.C.

Blog/Question of the Week: Ask our Experts: Oregon cannabis harvest projections for 2019

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-9-29-2019/>

09/21/2019 New Frontier Data, Washington D.C.

Report: U.S. Cannabis Report – 2019 industry outlook
(Contributing Author)

09/15/2019 New Frontier Data, Washington, D.C.

Blog/Question of the Week: Ask our Experts: The Southern Hemp Expo

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-9-15-2019/>

08/25/2019 New Frontier Data, Washington, D.C.

Blog: Wholesale Comparison: Colorado vs. Oregon

<https://newfrontierdata.com/marijuana-insights/wholesale-comparisons-colorado-vs-oregon/>

08/11/2019 New Frontier Data, Washington, D.C.

Blog: “Are your Numbers in Order: Preparing your Cannabis Business for Turbulent Times Ahead”

<https://newfrontierdata.com/marijuana-insights/askourexperts81119/>

08/04/2019 New Frontier Data, Washington, D.C.

Blog/Question of the Week: What is an example of your involvement with government authorities?

<https://newfrontierdata.com/marijuana-insights/involvement-with-government-authorities/>

06/10/2019 New Frontier Data, Washington, D.C.

Blog: Utilizing Legal Cannabis for Sustainable Stimulus Begins Taking Root In Africa

<https://www.benzinga.com/markets/cannabis/19/06/13886203/utilizing-legal-cannabis-for-sustainable-stimulus-begins-taking-root-in-africa>

05/23/2019 New Frontier Data, Washington, D.C.

Report: Cannabis in Zimbabwe 2019: Opportunities, Risks, and Potential Economic Impact (Phase 2)

04/28/2019 New Frontier Data, Washington, D.C.

Blog: Ask Our Experts 4/28/2019: What did I miss at this month’s International Cannabis Business Conference (ICBC) in Berlin?

<https://newfrontierdata.com/tag/cannabinoids/>

04/15/2019 Cohn Reznick

Blog: 5 factors to Consider before Making a Cannabis Acquisition

<https://www.cohnreznick.com/insights-and-events/insights/5-key-factors-to-consider-before-making-a-cannabis-acquisition>

03/31/2019 New Frontier Data, Washington, D.C.

Blog / Question of the Week: California Business Environment Since Rollout of Statewide Adult-Use Program

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-3-31-2019-californias-business-environment-since-rollout-of-statewide-adult-use-program/>

03/29/2019 Cohn Reznick, New Frontier Data, Washington, D.C.

Blog: 6 Ways Cannabis Companies Can Maximize Their Sale Price

<https://www.cohnreznick.com/insights-and-events/insights/6-ways-cannabis-companies-can-maximize-their-sale-price>

03/10/2019 New Frontier Data, Washington, D.C.

Blog: Ask Our Experts 3/10/2019: What’s the Latest from the Latin American Markets?

<https://newfrontierdata.com/marijuana-insights/whats-the-latest-from-the-latin-american-markets/>

03/03/2019 New Frontier Data, Washington, D.C.

Blog: Ask Our Experts 3/03/2019: What are the implications of Mexican adult-use legalization

<https://newfrontierdata.com/marijuana-insights/ask-our-experts-3-03-2019-what-are-the-implications-of-mexican-adult-use-legalization/>

02/10/2019 New Frontier Data, Washington, D.C.

Blog: Ask Our Experts 2/10/2019: Why A Cannabis LLC Beats a C-Corp

<https://newfrontierdata.com/marijuana-insights/why-a-cannabis-llc-beats-a-c-corp/>

02/09/2019 New Frontier Data, Washington, D.C.

Blog: How Alleged WHO Recommendations Would Affect International Cannabis Markets

<https://newfrontierdata.com/marijuana-insights/how-alleged-who-recommendations-would-affect-international-cannabis-markets/>

01/13/2019 New Frontier Data, Washington, D.C.

Blog / Question of the week: The Impact of Excess Cannabis Inventory in Oregon and Other Regulated Markets

<https://newfrontierdata.com/marijuana-insights/the-impact-of-excess-cannabis-inventory/>

01/06/2019 New Frontier Data, Washington, D.C.

Blog: Ask Our Experts: The Federal Reserve and Fears of Recession

<https://newfrontierdata.com/marijuana-insights/what-happens-to-cannabis-in-a-recession/>

2018

12/13/2018 New Frontier Data, Washington, D.C.

Report: Cannabis in Zimbabwe 2019: Medical and Industrial Applications in Implications (Phase 1)

10/24/2018 New Frontier Data, Washington, D.C.

Report: The Cannabis Energy Report 2018

10/01/2018 MSN News, New Frontier Data, Washington, D.C.

Blog: Capturing The Energy Costs For Cannabis Cultivation

<https://www.msn.com/en-us/news/technology/capturing-the-energy-costs-for-cannabis-cultivation/ar-BBNNQsX>

09/30/2018 New Frontier Data, Washington, D.C.

Blog: Capturing The Energy Costs For Cannabis Cultivation

<https://newfrontierdata.com/marijuana-insights/capturing-the-energy-costs-for-cannabis-cultivation/>

08/30/2018 New Frontier Data, Washington, D.C.

Blog: Identifying the Relative Value of a Cultivator License, By State

<https://dev.newfrontierdata.com/marijuana-insights/identifying-relative-value-cultivator-license-state/>

08/28/2018 New Frontier Data, Washington D.C.

Report: Cannabis and Native Populations: Potential Impact on North American Tribal Economies

08/09/2018 New Frontier Data, Washington, D.C.

Blog: New energy regulations may lead to cannabis supply shortages in MA

<https://newfrontierdata.com/marijuana-insights/new-energy-regulations-may-lead-cannabis-supply-shortages-ma/>

05/28/2018 New Frontier Data, Washington D.C.

Report: Cannabis in the U.S. Economy 2018: Jobs, Growth and Tax Revenue

06/26/2018 New Frontier Data, Washington D.C.

Report: The Canada Cannabis Report: 2018 Industry Outlook

03/24/2018 New Frontier Data, Washington, D.C.

Blog: The Apoc-Eclipse's Shining on Oregon's Cannabis Market

<https://newfrontierdata.com/marijuana-insights/on-oregons-cannabis-market-and-dollar-signs-of-the-apoc-eclipse/>

03/24/2018 New Frontier Data, Washington, D.C.

Blog: Discussing Proven Methods and Occasional Madness in Forecasting State Tax Revenues

<https://dev.newfrontierdata.com/marijuana-insights/shedding-some-light-on-the-occasionally-dark-arts-of-forecasting-state-tax-revenues/>

03/23/2018 New Frontier Data, Washington, D.C.

Blog: In Canada, Trudeau's Per-Gram Tax Would Make Less Sense Than Legitimate Sales

<https://newfrontierdata.com/marijuana-insights/why-trudeaus-per-gram-tax-would-make-less-sense-than-legitimate-sales/>

01/08//2018 New Frontier Data, Washington D.C.

Report: Cannabis in the U.S. Economy 2017: Jobs, Growth and Tax Revenue

2017

12/02/2017 New Frontier Data, Washington D.C.

Blog: Can Constellation Brands' Entry into the Market Lead to Banking Reform?

<https://newfrontierdata.com/marijuana-insights/can-constellation-brands-entry-market-lead-banking-reform/>

10/17/2017 New Frontier Data, Washington D.C.

Blog: Keeping a Cool Head About California's Post-Wildfires Market and Prices

<https://newfrontierdata.com/marijuana-insights/keeping-a-cool-head-about-californias-post-wildfires-market-and-prices/>

07/16/2017 New Frontier Data, Washington, D.C.

Blog: Shedding Some Light on the (Occasionally) Dark Arts of Forecasting State Tax Revenues

<https://newfrontierdata.com/marijuana-insights/shedding-light-occasionally-dark-arts-forecasting-state-tax-revenues/>

06/17/2017 New Frontier Data, Washington, D.C.

Blog: Former Mexican President Fox Fires Up NCIA Crowd

<https://newfrontierdata.com/marijuana-insights/former-mexican-president-fox-fires-up-the-crowd-at-ncia/>

05/13/2017 New Frontier Data, Washington, D.C.

Report: “The Cannabis Industry 2.0: Charting the Next Stage in Cannabis Investing Following the Historic 2016 U.S. Elections”

04/27/2017 New Frontier Data, Washington, D.C.

Whitepaper: “An Analysis of the Impact of §280e taxation on the US Cannabis Industry” An analysis of 280e tax policy on cannabis businesses.

04/17/17 Whitney Economics, Portland, OR

Whitepaper: “*Analysis of (Oregon) SB1047*” Provided analysis to Oregon state Judiciary Committee on a proposed legislation on an Oregon interstate cannabis compact bill. (04/17/17)

04/09/2017 New Frontier Data, Washington, D.C.

Blog: Cultivating Awareness About The Expanding, Diverse Market for Hemp

<http://blog.newfrontierdata.com/marijuana-insights/cultivating-awareness-expanding-diverse-market-hemp>

04/02/17 Whitney Economics, Portland, OR

Whitepaper: “*Testing Costs and the Impact on the Oregon Cannabis Market*” Examined increased test costs on wholesale and retail prices and the correlation to the decrease in Oregon tax revenue

04/02/17 New Frontier Data, Washington, D.C.

Book: “*Cannabis Industry Annual Report*”, 2017 New Frontier Data, Senior Economist (04/17)

03/17 BDS Analytics, Arcview, Denver, Colorado

Book: “*The State of the Legal Marijuana Market*”, 2017 ArcView Market Research, Chief Economist (BDS Analytics, 03/17)

03/17 Whitney Economics, Portland, OR

Whitepaper: “*Taxation and the Effects on the Illicit Cannabis Market*” An analysis of proposed legislation to increase Oregon cannabis taxes by 5%. Demonstrated the resulting illicit market increase and overall tax decrease

02/22/17 Whitney Economics, Portland, OR

Whitepaper: “*Cannabis Employment Estimates*” Presented to the Oregon House Committee on Economic Development and Trade (02/22/17)

2016

12/08/16 Whitney Economics, Portland, OR

Whitepaper: “*The Lack of City of Portland Licenses Set to Impact on the Oregon Cannabis Market, an Analysis of the Office of Neighborhood Involvement Marijuana Program Statistics*”

12/02/16 Whitney Economics, Portland, OR

Whitepaper: “*Test Changes and the Impact to the Oregon Cannabis Market: Results of a Survey by Whitney Economics*” Analysis of the economic impact of test changes on supply and tax revenues

08/22/2016 Whitney Economics, Portland, OR

Whitepaper: “*The Economic Impact of Measure O in San Bernardino, California*” an economic analysis of ballot measure “O” to allocate specific areas of the city of San Bernardino for cannabis business development (08/22/16)

08/09/2016 Whitney Economics, Portland, OR

Whitepaper: *"The Clinch on Cannabis"*, an analysis of the Washington State cannabis market and the proposed expansion to 522 retail outlets. Presented at a conference in Bellevue, Washington (08/09/16)

06/30/2016 Whitney Economics, Portland, OR

Whitepaper: *"Cannabis Economics and its Role in Shaping Public Policy"* Presented at the Western Economic Association International (WEAI) conference in Portland, Oregon (06/30/16)

03/2016 Whitney Economics, Portland, OR

Whitepaper: *"Oregon Cannabis Jobs Report"* A survey based research project on retail cannabis jobs in Oregon (03/2015). Findings featured in USA Today and Associated Press Wire

02/02/16 Whitney Economics, Portland, OR

Whitepaper: *"The Impact of the Proposed Moratorium Referendum on Golden Leaf Holdings and the Marion County Economy"* Public testimony to Marion County Board of Commissioners on the economic impact of a proposed moratorium

2015

06/15/15 Whitney Economics, Portland, OR

Whitepaper: *"The Economic Impact of Proposed legislation to Reduce Plant Counts in the Oregon Cannabis Market"* Testimony to the joint legislative committee on implementing measure 91

06/03/15 Whitney Economics, Portland, OR

Whitepaper: *"Oregon Cannabis Demand Forecast Analysis"* Provided testimony to the Oregon state joint legislative committee for implementing measure 91 on the total projected demand (in pounds) of cannabis flower in the state of Oregon

05/20/2015 Whitney Economics, Portland, OR

Whitepaper: *"Recreation Tax Policy Analysis and Recommendations"* Provided testimony to the Oregon state legislature on adopting a point of sales tax versus a weight-based tax

2014

07/30/2014 Whitney Economics, Portland, OR

Whitepaper: *"Price Tag Inputs on Initiative 53"*, public testimony presenting a tax revenue forecast for the Oregon cannabis market on measure 91 the adult use cannabis legalization referendum in Oregon



Office of Cannabis Management

KATHY HOCHUL
Governor

FELICIA A. B. REID
Acting Executive Director

Federal Marijuana Rescheduling DEA Hearing Notice

Date: September 30, 2024

Drug Enforcement Administration, Attn: Anne Milgram, Administrator

Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152

Subject: Notice of Appearance

Please take notice that members of the New York Office of Cannabis Management will appear in the matter of: Docket No. DEA-1362; A.G. Order No. 5931-2024 / Schedules of Controlled Substances: Rescheduling of Marijuana.

(A) (State with particularity the interest of the person in the proceeding.).

The New York State Office of Cannabis Management (OCM) is filing a written notice of intention to participate in the hearing process with the United States Drug Enforcement Administration to provide evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances as published in the Federal Register (Vol. 89, No. 166, August 29, 2024) on or near December 2, 2024.

New York has a long-standing medical cannabis program and legalized adult-use cannabis in 2021 under the Marijuana Regulation and Taxation Act (MRTA). The MRTA established a framework prioritizing public health, safety, and social equity – including automatic expungement of criminal records for cannabis-related offenses and directing 40% of adult-use tax revenue to communities disproportionately impacted by cannabis prohibition. Therefore, the state is interested in the proceeding to provide evidence and expert opinion on this matter.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

The objections and issues concerning the OCM that are not addressed with rescheduling alone include but are not limited to:

- **Federal cannabis criminalization remains:** While moving cannabis to Schedule III will meaningfully advance the federal legalization of cannabis, removing marijuana from the Controlled Substances Act would end the federal criminalization of cannabis, reduce research barriers and ultimately support current state cannabis regulatory frameworks.
- **Alignment of cannabis and hemp product regulations:** Clarification and harmonization of the regulations for cannabis and hemp-derived intoxicating products is critical for consumer safety and regulatory consistency across the country.

- **National standards for cannabis regulatory implementation and data collection efforts:** Federal support and participation is key to standardizing and enhancing data collection efforts, ensuring states have the resources to monitor public health and safety impacts of cannabis legalization. Establishing consistent, evidence-based health and safety standards for areas including but not limited to cannabis cultivation practices, manufacturing, packaging, labeling, advertising and marketing, distribution, retail, product testing and worker safety standards to protect consumers, the cannabis workforce and the environment is imperative.
- **Access to financial services:** Banking reform is necessary to allow cannabis businesses to operate safely, transparently and successfully.
- **Federal Cannabis Community Reinvestment and Research Fund:** Federal funds should be allocated to support cannabis research and provide businesses development resources to community's disproportionality impacted by prohibition.
- **Veteran medical cannabis access:** The veteran community, who are a priority social and economic equity group, remain barred from using medical cannabis for risk of losing access to VA benefits.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

The OCM supports the DEA and DOJ proposal to reschedule marijuana under the Controlled Substances Act (CSA), as outlined in the Federal Registrar Notice. Rescheduling cannabis from Schedule I to Schedule III acknowledges the medicinal value of cannabis, aligns with the recommendations from the Department of Health and Human Services (HHS), and reflects the views of 88% of Americans who support cannabis legalization.

Current federal policy, specifically around banking and taxation have undermined the growth and performance of legal regulated markets. While the benefits of rescheduling may include reinforcing the importance of cannabis in medical treatments, reducing stigma, encouraging healthcare providers to consider cannabis as a therapeutic option, potential banking reform and a reduction of restrictions associated with cannabis research – there are still additional issues that the OCM would like to see addressed by the Drug Enforcement Administration in the federal cannabis regulatory process.

The OCM confirms their intention to participate in the federal rescheduling hearing process to support rescheduling cannabis and urge the federal government to provide guidance that prioritizes people over profits, expands social equity programs, ensures the stability of state regulated cannabis programs, enhances financial access for cannabis business and supports public health & safety to create a thriving, equitable cannabis market that benefits those most disproportionality impacted by cannabis prohibition, cannabis consumers, and local communities in kind.

All notices to be sent pursuant to this appearance should be addressed to:

Name: Felicia A. B. Reid, Esq.

Street Address: 1220 Washington Avenue, Building 9, 4th Floor • Albany, New York 1226

Schedules of Controlled Substances: NY OCM Rescheduling of Marijuana Public Comment (July 2024)

The New York State Office of Cannabis Management (OCM) extends its support to the Drug Enforcement Administration (DEA) and Department of Justice (DOJ) in reevaluating marijuana's status under the Controlled Substances Act (CSA). This historic step reflects the growing consensus that cannabis should be regulated and accessible for both medical and adult-use purposes, aligning with the views of 88%¹ of Americans who support cannabis legalization. New York State has had a state-run medical cannabis program for a decade and legalized adult-use cannabis in 2021, regulating the cannabis industry in a manner that protects public health and safety. Federal rescheduling of marijuana from Schedule I to Schedule III acknowledges its medicinal value, consistent with recent recommendations from the Department of Health and Human Services (HHS). ^{(b)(6)}

OCM requests additional guidance from the federal government, like the Cole Memorandum (2013) which signaled the federal government's enforcement priorities and commitment to allow states to regulate cannabis by their state-run programs. New York's cannabinoid hemp, adult-use, and medical cannabis programs include hundreds of licensees and over 100,000 medical cannabis patients, who depend on access to regulated cannabis. Rescheduling marijuana to Schedule III would be a positive change, however state regulated cannabis programs need surety from the federal government that these programs will remain stable and accessible to consumers even as the federal government develops and issues guidance areas unaddressed by rescheduling alone.

I. Impact of Prohibition and the New York Marijuana Regulation and Taxation Act

New York State enacted the Marijuana Regulation Taxation Act (MRTA) in March 2021. The MRTA created OCM and established a comprehensive regulatory structure to oversee the licensure of state-based businesses that engage in the cultivation, production, distribution, sale, and taxation of medical cannabis; adult-use cannabis; and cannabinoid hemp. The MRTA:

- Established a robust social and economic equity program to actively encourage members from communities disproportionately impacted by the policies of marijuana prohibition to participate in the new industry,
- Created a process to automatically expunge criminal records for cannabis-related offenses, and
- Developed a community reinvestment fund to direct 40% of adult-use cannabis tax revenue to communities that had been most disproportionately impacted by cannabis prohibition.

These initiatives aimed to address the social and economic harm caused by decades of disproportionately applied drug policies and provide accessible, equitable opportunities within a legal cannabis framework. Today, New York has one of the highest rates of social equity licensees operating cannabis businesses in the country.

II. Advantages of Rescheduling and Considerations for State-Regulated Cannabis Operations

Rescheduling cannabis from Schedule I to Schedule III is a policy shift that impacts several sectors of the cannabis industry, including the medical cannabis, tax policy, and research.

- **Medical Use:** Rescheduling underscores the importance of medical cannabis use. This recognition may help reduce the stigma associated with cannabis, encouraging more practitioners to acknowledge and utilize it as a potential treatment option.
- **Industry Participation and Taxation:** Businesses currently involved in the cannabis industry cannot deduct standard business expenses due to Section 280E of the Internal Revenue Code, which applies

to Schedule I and II substances. Rescheduling cannabis to Schedule III would remove this restriction, allowing the cannabis industry to deduct business expenses such as payroll, rent, and marketing. This action has the potential to make licensed cannabis operators more competitive with the unregulated market which does not adhere to New York's cannabis safety regulations or pay product taxes – undermining community reinvestment and the public health and safety goals of legalization.

- **Research:** Researchers are routinely unable to secure federal grants for studies involving Schedule I substances. State institutions have tried to fill the gap, but concerns exist that engaging in cannabis research, even if solely state-funded, could jeopardize those institutions' federal funding. This limits the scope of research to mostly privately funded initiatives, which can be sporadic and insufficient. Rescheduling to Schedule III would alleviate these barriers by easing research regulations and broadening funding opportunities.

Rescheduling cannabis to Schedule III signals federal intent for substantial policy and practice change and opens the door for additional federal guidance to support state-run cannabis programs. Of several issues that persist, however, are federal criminalization of adult-use cannabis, limited interstate commerce, persistent banking challenges, and continuity of care for medical cannabis patients. While rescheduling may open pathways for prescription drug models, ambiguity remains for many adult-use cannabis products. In addition, the federal government should consider addressing and eliminating criminal penalties associated with the possession, cultivation, manufacture, and distribution of cannabis, in line with states' frameworks. Further considerations should aim to expand equitable financial access and resources and solicit feedback from states on approaches whereby the federal government can best support state-regulated adult-use cannabis programs.

III. Considerations for Further Comprehensive Federal Cannabis Action

OCM recommends that the DOJ and DEA consider the following:

- **Establish National Standards for Agricultural Chemicals in the Cannabis Supply Chain:** Rescheduling presents an opportunity for the federal government to establish health and safety standards, tolerances, and permissible exposure limits for pesticides and other agricultural chemicals throughout the cannabis supply chain—from exposure during cultivation to exposure during cannabis consumption. The federal government has established such standards for the hemp industry,¹ however the use of agricultural chemicals in cannabis currently relies on a patchwork of variable state standards. Consistent, evidence-based standards will support the health and safety of workers, consumers, and the environment and facilitate compliance for the industry. Federal-state partnerships can support research into both the health and safety standards themselves as well as the impact of regulation of agricultural chemicals in the cannabis industry.
- **Ensure Access to Financial Services and Products:** Access to financial services and products is crucial for the sustainability and growth of the cannabis industry, especially for small businesses and social equity programs. Reforms allowing cannabis businesses to use traditional banking would eliminate the need for cash-only operations, which pose security risks and complicate financial management. Without traditional banking, cannabis businesses will continue to struggle in securing capital, building credit histories, and accessing essential financial support. Comprehensive cannabis banking reform would support public health and safety by encouraging consumers to purchase from regulated businesses, facilitate financial transparency, provide grants, low-interest loans, and business development resources to entrepreneurs from communities impacted by prohibition to foster a fair and equitable market.

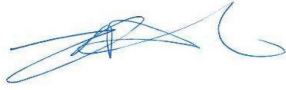
¹ U.S. Environmental Protection Agency. (2020). *Pesticide Products Registered for Use in Hemp*.
https://19january2021snapshot.epa.gov/pesticide-registration/pesticide-products-registered-use-hemp_.html

- **Standardize Data Collection and Support Monitoring of Cannabis-Related Outcomes:** State cannabis legalization has far-reaching effects and requires diverse data sources to assess its impact on public health and safety. A robust monitoring plan incorporating population-based surveys, healthcare data, and motor vehicle crash data is crucial for evidence-based policy. Resources are needed to address limitations in existing data systems to accurately quantify cannabis's role in outcomes and differentiate between regulated and unregulated cannabis impacts. For example, the Fatality Analysis Reporting System (FARS) includes drug testing results, but a positive cannabis test does not necessarily indicate impairment. Similarly, cannabis-related ICD-10 codes identify use or dependence in healthcare encounters without indicating causality. Professional organizations like the Council of State and Territorial Epidemiologists are working to standardize definitions of cannabis-related emergency visits and hospitalizations, however further analysis is needed to ensure accurate data presentation and help state regulators understand the impacts to create further cannabis policy. Statewide data collection is expensive, and these costs can be a barrier to data collection in some states. Federal funding support and data standardization would ensure states have access to better, more comparable data for national analysis to monitor public health and safety trends across jurisdictions.
- **Enhance Cannabis Research Accessibility:** Allowing researchers to access commercially available cannabis products from state-licensed operators would enable the scientific investigation and data collection of real-world products utilized by consumers. Expressly permitting academic institutions, particularly if their programs are supported by federal monies, to conduct these studies without concern of losing federal benefits, will be a significant step in advancing cannabis research.
- **Address the Regulation of Cannabis and Intoxicating Hemp Products:** The current misalignment of the treatment of cannabis and hemp-derived intoxicating products is untenable for state regulators. States require clarity to set product quality control standards for all cannabis products, regardless of whether they were originally derived from hemp or cannabis. This is a major public health concern as similar products are operating under different regulatory frameworks creating significant confusion for regulators, businesses, and cannabis consumers.
- **Remove Cannabis from the Controlled Substances Act:** Removing cannabis from the Controlled Substances Act would eliminate federal criminalization, reduce barriers to cannabis research, and create a pathway for states that have enacted laws to authorize the production, distribution and possession of cannabis to continue to do so. Establishing evidence-based definitions for "potential for abuse"² and "currently accepted medical use"² based on contemporary research^{1,2} will help to ensure cannabis is regulated according to its actual risks and benefits, promoting evidence-based drug policy.
- **Establish a Federal Cannabis Community Reinvestment and Research Fund:** Allocating federal funds to research the potential therapeutic benefits of cannabis, as well as financing and providing business development resources to entrepreneurs disproportionately impacted by cannabis prohibition is necessary for advancing the scientific understanding of cannabis and supporting social equity cannabis programming across the country.

In conclusion, the State of New York strongly supports rescheduling cannabis from Schedule I to Schedule III. In addition, OCM urges the federal government to provide clear guidance to protect state-level adult-use cannabis programs, improve financial access and resources, and expand the health and safety opportunities of cannabis study. These measures will ensure a thriving, equitable cannabis market that works in benefit of consumers, businesses, researchers, and local communities in kind.

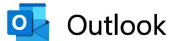
² U.S. Code. (1970). Controlled Substances Act, 21 U.S.C. § 801 et seq.

Kind regards,



Felicia A. B. Reid, Esq.

Acting Executive Director / Executive Deputy Director



Outlook

[EXTERNAL] Drug Enforcement Administration, Attn: Administrator - Federal Marijuana Rescheduling Hearing Request

From Cahill, Olivia (OCM) <Olivia.Cahill@ocm.ny.gov>**Date** Mon 9/30/2024 5:34 PM**To** NPRM <NPRM@dea.gov>**Cc** Reid, Felicia (OCM) <Felicia.Reid@ocm.ny.gov>; Kagia, John (OCM) <John.Kagia@ocm.ny.gov>; Rosa, Nicole (OCM) <Nicole.Rosa@ocm.ny.gov>; Hunt, Lyla (OCM) <Lyla.Hunt@ocm.ny.gov>; Fitzpatrick, Rachel (OCM) <Rachel.Fitzpatrick@ocm.ny.gov>; Hans-Cohen, Alana (OCM) <Alana.Hans-Cohen@ocm.ny.gov>

1 attachment (255 KB)

NY Office of Cannabis Management Rescheduling of Marijuana Hearing Notice.pdf;

Greetings,

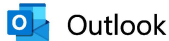
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Attached is the PDF with the language prescribed in [21 CFR 1316.48](#) surrounding intention of members from The New York Office of Cannabis Management to participate in the hearing process.

Thank you for your consideration.



Olivia Cahill
(she/her)
Program Analyst | Policy
Olivia.cahill@ocm.ny.gov
59 Maiden Lane, NY 10038
[Cannabis.ny.gov](#) | [OCM Newsletter](#)



Outlook

[EXTERNAL] Drug Enforcement Administration, Attn: Administrator - Federal Marijuana Rescheduling Hearing Request

From Cahill, Olivia (OCM) <Olivia.Cahill@ocm.ny.gov>**Date** Mon 9/30/2024 5:34 PM**To** NPRM <NPRM@dea.gov>**Cc** Reid, Felicia (OCM) <Felicia.Reid@ocm.ny.gov>; Kagia, John (OCM) <John.Kagia@ocm.ny.gov>; Rosa, Nicole (OCM) <Nicole.Rosa@ocm.ny.gov>; Hunt, Lyla (OCM) <Lyla.Hunt@ocm.ny.gov>; Fitzpatrick, Rachel (OCM) <Rachel.Fitzpatrick@ocm.ny.gov>; Hans-Cohen, Alana (OCM) <Alana.Hans-Cohen@ocm.ny.gov>

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Thank you for your consideration.



Olivia Cahill
(she/her)
Program Analyst | Policy
Olivia.cahill@ocm.ny.gov
59 Maiden Lane, NY 10038
[Cannabis.ny.gov](#) | [OCM Newsletter](#)

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Subject: Notice of Appearance

Dear Administrator:

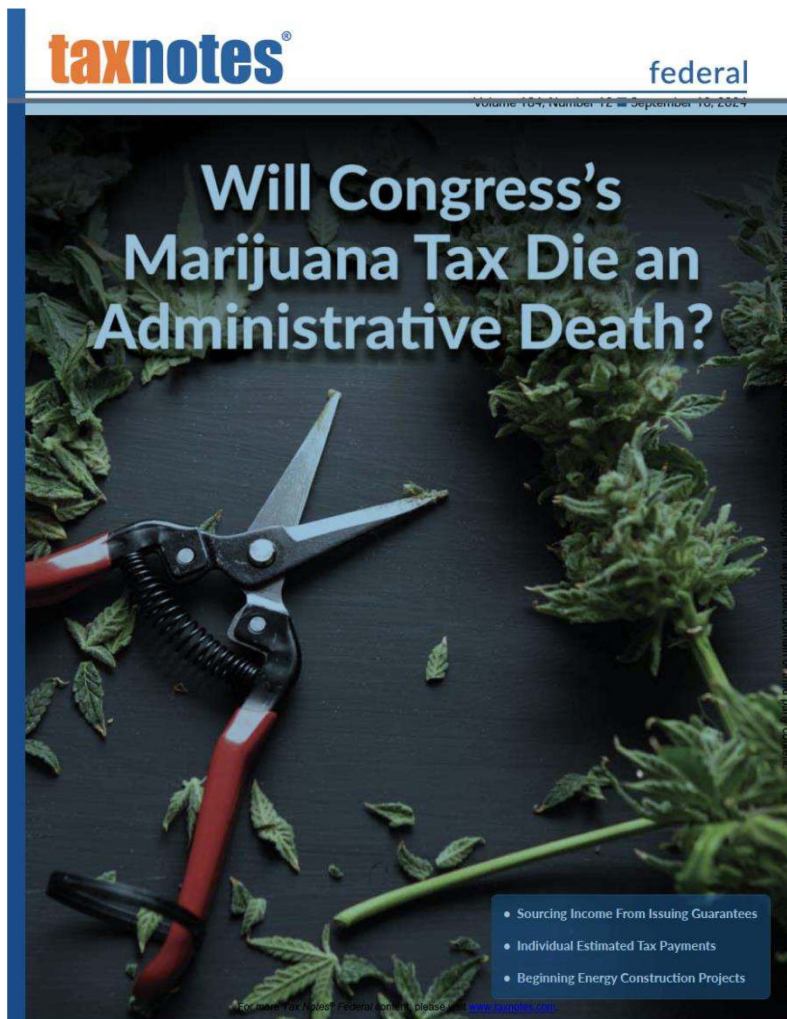
Please take notice that Patrick Oglesby would like to appear in the matter of the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act on December 2, 2024, as announced here: <https://www.federalregister.gov/documents/2024/08/29/2024-19370/schedules-of-controlled-substances-rescheduling-of-marijuana>

(1) State with particularity the interest of the person in the proceeding;

My interest in **tax policy** causes my interest in this proceeding – pro bono publico. The peculiar marijuana selling expense tax known as 280E would go away with Schedule III, since section 280E of the Internal Revenue Code, by its terms, burdens commerce only in Schedule I and II drugs.

You raised non-drug issues in your May announcement: “DOJ acknowledges that there may be large impacts related to **Federal taxes** . . . among other things. DOJ is specifically soliciting comments on the economic impact of this proposed rule.” A secondary issue goes to economic impact -- the impact of a tax cut on the competitive positions of large and small cannabis businesses.

My analysis of the tax implications of rescheduling, “Will Congress’s Marijuana Tax Die an Administrative Death?,” was the cover story in the September 16 issue of Tax Notes magazine. <https://www.taxnotes.com/tax-notes-federal/exemptions-and-deductions/will-congresss-marijuana-tax-die-administrative-death/2024/09/16/715lm>.



I'm a former staff lawyer for the Joint Committee on Taxation and the Senate Finance Committee, and lead a tax policy non-profit, the Center for New Revenue, which has focused on the intersection of tax policy and drug policy. I have worked for various states and non-profits on cannabis taxation and economics, but **never** for the cannabis industry.

- (2) State with particularity the objections or issues concerning which the person desires to be heard;

Because rescheduling would bring cannabis outside the ambit of Internal Revenue Code section 280E, which applies a special tax burden only to Schedule I and II drugs, my main issue is whether the Administration should **cut taxes** on marijuana businesses.

- (3) State briefly the position of the person regarding the objections or issues.

For tax policy, I do not support Schedule III for marijuana. If you move away from Schedule I as inappropriate drug policy, Schedule II, retaining the 280E tax, would be more appropriate for tax policy than Schedule III. (I claim no expertise on non-economic matters, and have no opinion on whether Schedule II's "high potential for abuse and/or addiction" is more fitting than Schedule III's "low to moderate potential for abuse and/or addiction.")

A **federal marijuana tax seems desirable** and ultimately inevitable -- despite the state-legal marijuana industry's competitive struggles with the illicit market and with hemp THC drug sellers. Those struggles are vastly different among states, some of which have marginalized them. Meanwhile, for public health, the section 280E selling expense tax may be the best marijuana tax available. It nudges against advertising and marketing, which are often frills at best and demand-creators at worst. Schedule III would tax marijuana like tomatoes. In any realistic medium-term scenario, Congress would not tax marijuana like tomatoes.

A good marijuana tax is hard to find, so **it would be sad to see Congress's pro-public-health, revenue-positive section 280E selling expense tax die** by marijuana's administrative transfer to Schedule III. However, marijuana's transfer to Schedule II instead of Schedule III would keep the marijuana selling expense tax revenue coming in and would keep section 280E's unfinished tax experiment running.

I suggest that as you balance tax competing concerns, and that that balance tilts against Schedule III. Now the tax question is a close one, and your drug policy analysis involves much more than tax and economic issues. But I am glad that you are looking at those tax and economic issues, and **I hope my nuanced views will help you.**

Thank you.

All notices to be sent pursuant to this appearance should be addressed to:

Patrick Oglesby

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September 30, 2024

VIA ELECTRONIC SUBMISSION – NPRM@DEA.GOV

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Re: Notice of Appearance (Docket No. DEA-1362)

Administrator Milgram:

Please take notice that American Trade Association for Cannabis and Hemp (“ATACH”) requests to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the “Proposed Rule”), if the Drug Enforcement Administration (“DEA”) grants ATACH’s request to participate in the hearing scheduled for December 2, 2024.¹

(A) ATACH has standing to participate in a hearing. ATACH is an “interested person” and falls within the CSA’s zone of interests. Further, ATACH and its members will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized. ATACH’s status as an “interested person” is further detailed in the enclosed submission.

(B) Among other things, ATACH has unique expertise and would provide invaluable insights into: (i) the impact of new marijuana-specific DEA controls on ATACH’s members, (ii) medical research involving marijuana, particularly as it relates to veterans’ access, (iii) abuse potential and public health risks of marijuana, (iv) effects on ATACH’s members who are minority-owned and small businesses and whose communities have been impacted by the War on Drugs, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. Further detail about the objections or issues on which ATACH desires to be heard is provided in the enclosed submission.

(C) ATACH represents a coalition of active participants in and around the state-legal cannabis industry that are directly and adversely affected by the Proposed Rule. ATACH is thus uniquely situated to assist DEA’s administrative decision making. ATACH and its members have extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated marijuana marketplace. DEA sought comments related to the practical

¹ ATACH previously submitted a timely Request to Participate in a Hearing and Notice of Appearance (the “First Request”) in response to the agency’s Proposed Rule. ATACH reserved the ability to supplement its First Request in response to the Administrator granting a hearing. The enclosed submission hereby supersedes ATACH’s First Request.

Administrator Milgram
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consequences of rescheduling marijuana. Proposed Rule at 44,621. ATACH is particularly well-suited to provide this insight, as it represents a broad coalition of interests, including (but not limited to) distributors, seed-to-sale technology providers, economic consultants, ingredient and garden care suppliers, financial service providers serving the cannabis industry, non-profit researchers, and veterans groups, among other voices. ATACH's positions with regard to the particular objections or issues are further detailed in the enclosed submission, which replaces the petition filed on June 17, 2024. Enclosed with ATACH's updated request to participate in the hearing is ATACH's public comment submitted on July 22, 2024, on behalf of its members.

All notices to be sent pursuant to this appearance should be addressed to the attorneys at the addresses provided below.

Respectfully yours,



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Enclosure



September 30, 2024

VIA ELECTRONIC SUBMISSION – NPRM@DEA.GOV

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Re: Request to Participate in a Hearing & Notice of Appearance (Docket No. DEA-1362)
Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597

***This updated petition supersedes and replaces ATACH's June 17, 2024 submission.**

Administrator Milgram:

Pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, the American Trade Association for Cannabis and Hemp ("ATACH") submits, as an "interested person," this Request to Participate in a Hearing and Notice of Appearance at the hearing scheduled for December 2, 2024. *See Notice of Hearing on Proposed Rulemaking*, 89 Fed. Reg. 70,148 (Aug. 29, 2024) ("Notice of Hearing").¹ This updated petition supersedes and replaces ATACH's June 17, 2024 submission. Pursuant to any pre-hearing scheduling order, ATACH will submit declarations supporting expert and fact witness testimony.²

ATACH is an Internal Revenue Service-recognized 501(c)(6) entity. ATACH's member companies and organizations include businesses, professional firms, research laboratories, and state trade associations involved in or serving the marijuana and hemp industries. ATACH and its member companies and organizations are "interested persons" within the zone of interests and will be "adversely affected" or "aggrieved" by this proposed rule, entitled *Schedules of Controlled Substances: Rescheduling of Marijuana*, if finalized. *See* 89 Fed. Reg. 44,597 (May 21, 2024) (the "Proposed Rule").

ATACH has standing to participate in a hearing. Among other things, ATACH has unique expertise and provides invaluable insights into (i) the impact of new marijuana-specific Drug Enforcement Administration ("DEA") controls on ATACH's members, (ii) medical research involving marijuana, particularly as it relates to veterans' access, (iii) abuse potential and public health risks of marijuana, (iv) effects on members who are minority-owned and small businesses

¹ ATACH previously submitted a timely Request to Participate in a Hearing and Notice of Appearance (the "First Request") in response to the agency's Proposed Rule. ATACH reserved the ability to supplement its First Request in response to the Administrator granting a hearing. ATACH hereby replaces its First Request.

² Attached as Exhibit A is a list of doctors and scientists prepared to testify as expert witnesses.

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and whose communities have been impacted by the War on Drugs, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. ATACH is prepared to present expert testimony on these issues as well as, *inter alia*, marijuana's currently accepted medical use in treatment in the United States, relevant international treaty obligations, and the placement of marijuana on the schedules of the Controlled Substances Act ("CSA"). ATACH's testimony would materially assist a DEA Administrative Law Judge ("ALJ") in preparing a sound and well-supported administrative decision.

A.

On May 21, 2024, the Department of Justice ("DOJ") issued the Proposed Rule. *Id.* at 44,597. The Proposed Rule noted that DEA may hold a hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances." *Id.* at 44,599 (cleaned up). The agency has decided to hold such a hearing. *See* Notice of Hearing, 89 Fed. Reg. at 70,148.

Concurrently, the agency is considering "marijuana-specific controls that would be necessary to comply with relevant treaty obligations in the event that, after the hearing, a final order reschedules marijuana." Proposed Rule at 44,599. DEA will presumably consider any such updated controls during this rulemaking.

This request to participate in a hearing is timely filed. As explained in the Notice of Hearing, interested persons must submit a notice of their intent to participate on or before September 30, 2024. This notice is provided within that time period.

This request to participate serves to inform DEA that ATACH is an interested person and intends to participate to the fullest extent possible in the agency's scheduled hearing. ATACH has separately submitted a public comment on the Proposed Rule on behalf of its members, the cannabis industry and its ancillary businesses, researchers, social equity license holders, medical providers, and medical patients, including veterans.³

B.

ATACH is a prominent national trade organization promoting the legal and regulatory framework for the marijuana and hemp industries in the United States in partnership with its member companies. Founded in 2014 in response to the evolving legal landscape governing marijuana and hemp, ATACH works to influence public policy, promote industry growth, and enhance the commercial environment for both industries. Based in Washington, D.C., ATACH collaborates closely with state and federal lawmakers, regulatory agencies, researchers, standards organizations, accreditation bodies, and industry stakeholders to foster a viable, safe, and regulated

³ ATACH's public comment is attached as Exhibit B.

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marijuana and hemp market with particular attention on public health and safety and consumer protection.

ATACH is particularly focused on areas such as product safety, industry standards, legislative advocacy, education, and research within the marijuana and hemp sectors. It provides its members with critical information on regulatory changes, market trends, and legal challenges. ATACH has a vested interest in seeing that its member companies succeed and that they are economically viable and in ensuring that Americans' use of marijuana and hemp products is safe and medicinally beneficial.

ATACH has spent extensive time, money, and other resources to advocate for a regulated, responsible marijuana marketplace. ATACH's interests and resource expenditures would be at risk if ATACH was not permitted to participate in the formal rulemaking process to the fullest extent permitted by law.

The Proposed Rule directly affects ATACH and its members. Specifically, ATACH and its members, including DEA-licensed marijuana researchers, may be subject to new DEA registration requirements as well as new DEA controls, such as potential new controls regarding the manufacturing and sale of marijuana. If DEA eschews the Proposed Rule and decides that marijuana should remain on schedules I or II, that decision would also adversely affect ATACH and its members with significant tax consequences, as well as by creating difficulty in testing state-regulated products, conducting medical research, assisting veterans, and supporting minority-owned and other small businesses.

C.

The Proposed Rule represents a sea change in how the federal government proposes to regulate the nation's marijuana market. As DEA is aware, marijuana is currently categorized as a schedule I substance, making it subject to the most stringent controls. Schedule I substances, according to DEA's classification, have no currently accepted medical use and a high potential for abuse. Some examples of schedule I drugs are heroin, LSD, ecstasy, and peyote.⁴

ATACH maintains that marijuana does not belong in schedules I or II, particularly given its accepted medical utility and demonstrated low potential for abuse. As detailed in the Proposed Rule, the Department of Health and Human Services ("HHS") conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III. 89 Fed. Reg. at 44,600. Specifically, HHS concluded that marijuana has a potential for abuse less than the other substances in schedules I and II, that marijuana has a currently accepted medical use in treatment in the United States, and that the abuse of marijuana may lead to moderate or low physical dependence or psychological dependence. *Id.*

⁴ DEA, *Drug Scheduling*, <https://www.dea.gov/drug-information/drug-scheduling>.

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In addition, 38 states, the District of Columbia, and four territories have legalized the use of medical marijuana to treat certain health conditions, including chronic pain. *Id.* In contrast, schedule II substances are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of schedule II drugs are cocaine, methamphetamine, methadone, oxycodone, and fentanyl.⁵

The public health risks of marijuana are not similar to the “comparator substances controlled” under schedules I and II reviewed in the Proposed Rule. ATACH’s participation in the administrative hearing process would demonstrate that the public health risk associated with marijuana compares favorably to those associated with substances in schedules I and II, like heroin (schedule I), cocaine (schedule II), or fentanyl (schedule II). *See* Proposed Rule at 44,614 (discussing HHS’ recommendation on this point); *see also id.* at 44,618 (noting that heroin, cocaine, and fentanyl were considered “comparator substances controlled” under schedules I and II). According to data from the Centers for Disease Control and Prevention (“CDC”), heroin, cocaine, and fentanyl are responsible for tens of thousands of fatalities in the United States annually.⁶ In fact, DEA has launched a public awareness campaign that even “One Pill” of fentanyl “Can Kill,” noting that two milligrams of fentanyl (an amount smaller than a pencil tip) can be deadly.⁷ Given its deadly nature, the risk profile of fentanyl—a schedule II substance—dwarfs that of marijuana. DEA itself recognizes that not a single death has been associated with marijuana overdose.⁸ ATACH has a significant interest in making certain that the administrative hearing includes the best, most current, and most accurate scientific knowledge.

While the Proposed Rule would reschedule marijuana to schedule III, certain crucial consequences of this momentous decision remain unanswered. ATACH and its members are well-positioned to present evidence addressing these unanswered questions. ATACH is a trade association with membership that includes many of the leading participants in the state-legal, regulated marijuana marketplace. Some of ATACH’s members are “plant touching” companies, some provide ancillary services to the state-legal industry, and some are nonprofit research and advocacy organizations. The Proposed Rule will, once finalized, directly affect ATACH and its constituent members. Among other things, “if marijuana is transferred into schedule III, DEA will continue to have authority to maintain its existing regulatory scheme . . . governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marijuana.” Proposed Rule at 44,620. *See also id.* at 44,621 (“If marijuana is transferred to schedule III, the regulatory controls applicable to schedule III-controlled substances would apply, as appropriate.”). In other words, ATACH and its members may be subject to new DEA registration requirements regarding the manufacturing of

⁵ DEA, *Drug Scheduling*, <https://www.dea.gov/drug-information/drug-scheduling>.

⁶ CDC, *Provisional Drug Overdose Death Counts*, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁷ DEA, *One Pill Can Kill*, <https://www.dea.gov/onepill>.

⁸ DEA, *Marijuana/Cannabis: Drug Fact Sheet* at 3 (April 2020), https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf.

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marijuana or marijuana products, as well as any other regulatory controls applicable to schedule III substances. Accordingly, ATACH requests to participate in the agency's upcoming hearing.

D.

ATACH has standing to participate in a hearing. ATACH is an “interested person” and falls within the CSA’s zone of interests. Further, ATACH and its members will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized.

1.

The Proposed Rule is a “scheduling action” issued under 21 U.S.C. § 811(a). Notice of Hearing at 44,598; *id.* at 44,621. The Administrative Procedure Act (“APA”), the CSA, and DEA regulations set out the governing standards for this scheduling action and related rulemaking proceedings. *See id.* at 44,598–99.

Under the APA, 5 U.S.C. § 555(b), “an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding” “[s]o far as the orderly conduct of public business permits.” DEA regulations accordingly provide that an “interested person” may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c).

DEA regulations, in turn, define “interested person” as “any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. § 811].” 21 C.F.R. § 1300.01(b).⁹ As the Proposed Rule was promulgated under 21 U.S.C. § 811(a), DEA’s definition of “interested person” may apply here. *See* Proposed Rule at 44,598; *id.* at 44,621. We note that DEA has not formally defined “adversely affected or aggrieved” for purposes of the definition of an “interested person.” *See In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022) at 2 (“ALJ Order”).¹⁰ In recent scheduling actions, however, DEA has argued that a person qualifies as an “interested person” only if such person can demonstrate the equivalent of Article III standing to pursue litigation in federal court. *See* ALJ Order at 4. ALJs have correctly rejected that argument, however, concluding instead that it is sufficient that a person falls within the CSA’s “zone of interests.” *See id.* at 5–6. As the discussion that follows demonstrates, ATACH qualifies as an interested person under either standard.

⁹ Pursuant to 21 C.F.R. § 1300.01(b), “person” includes “any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.”

¹⁰ The ALJ Order is attached as Exhibit C.

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2.

ATACH is an “interested person” for two primary reasons.

First, ATACH falls within the CSA’s “zone of interests.” In May 2022, a DEA ALJ concluded that the test for “adversely affected or aggrieved”—and consequently, “interested person”—was satisfied when the person fell within the “zone of interests” to be regulated by the CSA. ALJ Order at 10. The Supreme Court of the United States has explained that the “zone of interests” test is “not meant to be especially demanding” given Congress’ intent to “make agency action presumptively reviewable.” *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (citation omitted).

A party falls “within the zone of interests,” the ALJ explained, “if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question.” ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). With regard to the CSA, the Supreme Court has noted that the statute was enacted with “the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Oregon*, 546 U.S. 243, 250 (2005).

ATACH falls within the CSA’s zone of interests. To start, ATACH and its members are regulated by the Proposed Rule and the CSA. ATACH and its members are actively involved in the state-legal marijuana industry. Each day, ATACH and its members work to support the state-regulated market for marijuana and marijuana products and actively fight against the perils of the illicit marketplace and unregulated hemp-derived intoxicants. And as is further outlined below, ATACH and its members may see new marijuana-specific controls related to marijuana-related activities under the Proposed Rule. Proposed Rule at 44,620–21.

Second, ATACH and its members would be adversely affected or aggrieved by the Proposed Rule if finalized. ATACH and its members are prepared to present evidence on these facts at a hearing:

- ***The Impact of New Marijuana-Specific Controls on ATACH and its Members:*** Concurrent with this rulemaking, the agency is considering marijuana-specific controls associated with international treaty obligations. Proposed Rule at 44,599. The Office of Legal Counsel (“OLC”) concluded that “additional controls pursuant to the CSA’s regulatory authorities” may be necessary. OLC, *Questions Related to the Potential Rescheduling of Marijuana*, at 4 (Apr. 11, 2024).¹¹ New DEA controls would adversely impact how ATACH’s members operate and would impose new costs.

ATACH member MedPharm Research (“MedPharm”) holds a DEA schedule I researcher license that permits it to investigate the effects of marijuana and cannabinoids on

¹¹ This OLC opinion is attached as Exhibit D.

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neurodegenerative diseases such as Alzheimer's and Parkinson's. MedPharm values its DEA license and its collaborative relationship with DEA and believes a strong working relationship between MedPharm and DEA benefits both parties. Unfortunately, MedPharm now faces the prospect of new, different, and potentially burdensome regulatory compliance obligations under the new DEA controls being contemplated.

While MedPharm does not yet know any details regarding what "additional controls" DEA has in mind, any additional requirements beyond those applicable to schedule III substances generally would impose burdensome and costly regulatory barriers to the urgently needed research MedPharm seeks to complete. Such additional costs would, among other things, adversely impact MedPharm's current research projects, the day-to-day operation of the company's research arm, and the company's ability to undertake additional and equally urgent research projects going forward. These barriers to MedPharm's research endeavors will ultimately undermine public health and safety generally by delaying the development and FDA-approval of potentially life-saving marijuana-related treatments and impeding MedPharm's ongoing efforts to provide important public health and safety data on the marijuana products consumers are using under Colorado law. These injuries undermine MedPharm's business goals and its core mission more generally and thus provide an independent basis for MedPharm's interested person status even if Article III standards control.

It is possible that changes in DEA controls would adversely impact the current research being conducted by MedPharm, the operation of the company's research arm, and the costs associated with implementing new controls. Furthermore, changes in DEA controls for cannabis and cannabinoids could have negative impacts on potential funding sources and scientific discovery and prohibit research projects from further advancement. If DEA were to reschedule cannabis and change the requirements for schedule I researchers, it could negatively affect MedPharm's research capabilities by creating new and unnecessary requirements, particularly given that its research protocols have already been approved by DEA.

Additionally, by reducing the requirements for researchers generally, DEA might make it easier for others to begin research after MedPharm expended substantial resources to its current level of operation. This lowering of standards could have adverse effects on the quality of scientific discoveries being made while disincentivizing projects that might lead to novel disease treatments.

Moreover, MedPharm has invested several years of time and significant monetary resources into establishing the first-of-its-kind research and production facility. Currently, MedPharm has implemented Current Good Manufacturing Practices, Good Agricultural and Collection Practices, and ISO17025. It is also Hazardous Materials and Handling

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audited and accredited. In addition, MedPharm is an applicant from the first round of DEA Cannabis Bulk Manufacturing Licensing in 2016, and its application remains unresolved and pending for decision before DEA. MedPharm undertook substantial capital investments to obtain these accreditations and certifications to protect the quality of research and eventual FDA-approved marijuana-related treatments it intends to research and develop. New DEA controls could potentially jeopardize those ongoing efforts.

MedPharm has several research projects that are moving through the company's drug discovery pipeline. MedPharm has spent years collaborating with the University of Iowa's Department of Neurology, School of Public Health, and the Institute for Clinical and Translational Science to organize and prepare to conduct a unique clinical trial with marijuana. Additionally, the research team has several sources of research funding, such as grant funding from the Institute of Cannabis Research at Colorado State University-Pueblo, where MedPharm's team collaborates with research teams from CU-Anschutz and CU-Change at the University of Colorado-Boulder, investigating the product quality within the Colorado adult-use cannabis marketplace. Lastly, MedPharm has worked with Colorado State University on a recent National Institutes of Health application looking at intoxicated driving effects of co-administration of cannabis and alcohol in addition to working with Northwestern University examining the effects of cannabinoids on traumatic brain injuries. New DEA controls could affect each of these research projects, which have taken years to establish. For these many reasons, this DEA-registered schedule I marijuana researcher is uniquely positioned to provide important input on any such new DEA controls being contemplated at this hearing and should be granted an opportunity to be heard.

In addition to uncertainties around new DEA controls, MedPharm has serious equities in the scheduling classification itself. Whether DEA ultimately adopts the Proposed Rule and transfers marijuana to schedule III or rejects it in favor of some other classification, the regulatory requirements applicable to marijuana in the wake of that decision will bear directly on the work MedPharm is currently doing under its DEA registration.

While MedPharm supports DOJ's proposal to transfer marijuana to schedule III and believes that outcome to be a momentous step in the right direction for federal marijuana policy, its own view is that marijuana does not belong on the CSA's schedules at all. As such, unless DEA ultimately deschedules marijuana, any action it takes on the Proposed Rule would adversely affect MedPharm.

As long as marijuana remains listed as a controlled substance at all—regardless of what CSA schedule it is on—MedPharm will remain subject to arduous regulatory requirements that will require it to maintain registration with DEA to continue its work. Maintaining DEA registration to research a controlled substance is costly, and complying with the regulatory requirements associated with registration is even more so. While transferring

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marijuana to schedule III would relax a few of those requirements incrementally, MedPharm would still face significant additional costs of doing business because of marijuana's status as a controlled substance. It would therefore have no choice but to pay the high price of compliance or else risk criminal penalties under the CSA.

MedPharm would be especially aggrieved if DEA were to reject the Proposed Rule in favor of either maintaining marijuana's schedule I classification or transferring it to schedule II. A number of regulatory requirements applicable to schedule I and II substances are significantly stricter than those applicable to substances in schedule III, including, for example:

- Research with schedule I substances requires an FDA-approved protocol—an arduous and costly requirement that does not apply to research with substances in any other schedule. *See* 21 C.F.R. § 1301.18.
- The inventory requirements for substances in schedules I and II are significantly stricter than those applicable to substances in schedule III. *See id.* § 1304.11(e)(6).
- The export requirements that would apply to marijuana were it transferred to schedule III are significantly less strict than those that apply to it currently under schedule I. *See id.* § 1312.21.
- The restrictions on orders for schedule I and II substances are significantly stricter than those applicable to substances in schedule III. *See, e.g., id.* §§ 1305.04 and 1305.21.
- The storage requirements applicable to schedule I substances are significantly more burdensome than those that apply to substances in schedule III. *See id.* § 1301.71.

Each of these regulatory hurdles makes operations harder for MedPharm. Marijuana research is urgently needed, but conducting that research in compliance with federal law is extremely costly and time-consuming. Loosening these restrictions would therefore accelerate and enhance MedPharm's ability to complete its important work and enable it to take on additional projects. Costly regulatory burdens like these are precisely the sort of “injury in fact” that Article III courts routinely hold are sufficient to demonstrate that a party is adversely affected or aggrieved for purposes of assessing standing to bring suit in federal court. *See, e.g., Ass’n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 457–58 (D.C. Cir. 2012) (party not directly regulated by agency rule had standing based on increased compliance costs resulting from regulation of a different party); *Metro. Wash. Chapter, Associated Builders & Contrs., Inc. v. District of Columbia*, 62 F.4th 567, 573 (D.C. Cir. 2023) (“Miller & Long can bring this action in its own right based on its allegations that it incurs increased administrative costs to comply with the statute’s hiring and reporting requirements. . . .”) (citing cases).

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Finally, transferring marijuana to schedule III would reduce the stigma associated with handling and researching a schedule I substance while simultaneously eliminating the tax penalty associated with “trafficking” in marijuana under 26 U.S.C. § 280E. These shifts in public perception and tax penalties would free up significant capital for regulated marijuana companies and those interested in the safety and quality of products available in the state-regulated markets to invest in the sort of gold-standard, federally legal marijuana research that MedPharm has worked so hard to position itself to conduct. A DEA decision to keep marijuana in schedule I or transfer it to schedule II would therefore directly undercut MedPharm’s economic interests as well—another injury in fact sufficient to support interested person status even under the strictest Article III standard.

The potential effects of additional controls also extend to ATACH members who do not already hold a DEA license, such as testing laboratories, which are not currently required to do so under the state-regulated programs. Requiring them to register with DEA would be costly and arduous. DEA rules could also require that the agency play a role in the handling of final products, including burdensome paperwork, storage requirements, and methods of destruction. ATACH and its laboratory members may also be subject to new DEA registration requirements and controls applicable to schedule III substances. *See* Proposed Rule at 44,620–21. Compliance with these potential requirements could require increased staffing costs, costly modifications to laboratory facilities, and contracting with DEA-licensed disposal firms. Requiring laboratories to become DEA-licensed could also prevent them from accepting products from the state-licensed marijuana market as well as the hemp market, rendering their businesses obsolete. Thus, ATACH and its lab member companies are adversely impacted by the uncertainty surrounding the promulgation of new DEA controls or the enforcement of existing rules that currently remain unenforced. ATACH is prepared to produce affidavits from the Chief Scientific Officers of two of its member laboratories, ACT Labs and ProVerde Laboratories. These laboratories are not only within the zone of interests but are also aggrieved because of the uncertainties surrounding new or updated DEA controls.

Similarly, under the status quo, DEA does not enforce its regulatory requirements obligating cannabis labs to accept cannabis sample material only from other DEA-registered entities. This nonenforcement policy is essential to state-licensed labs, like ACT Labs and ProVerde Laboratories, because the vast majority of the entities submitting samples to cannabis labs nationwide are not themselves registered with DEA. And because these entities have handled cannabis in violation of federal law, DEA’s current policies effectively bar them from becoming registered even if they wanted to. Were DEA to enforce these policies in a post-rescheduling world, companies like ACT Labs and ProVerde Laboratories would be regulated out of existence in short order. Under traditional associational standing principles, their standing establishes ATACH’s standing as well. *See Students for Fair Admissions, Inc., v. Pres. & Fellows of Harvard Coll.*, 600 U.S. 181,

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198–201 (2023).

Another specific example involves ATACH members like PharmaCann, Inc., which serves the state-regulated *medical* marijuana market in particular. Despite the millions of patients and tens of thousands of licensed healthcare professionals using and recommending medical marijuana products in treatment across the country, the federal government had, until this administrative process, repeatedly insisted that marijuana had no currently accepted medical use in treatment in the United States. As a result, for federal law and U.S. treaty compliance purposes, the federal government had always insisted that the Single Convention’s regulating and reporting requirements with respect to the medical use of cannabis did not apply to the products being used in the state-regulated medical marijuana markets. The federal government’s recent acknowledgment in this rulemaking process that cannabis does, in fact, have medical utility undercuts the federal government’s longstanding rationale for treating these particular treaty requirements as inapplicable to state-regulated medical marijuana regimes. As such, ATACH members like PharmaCann, who serve and operate within the state-regulated medical marijuana space, now face the prospect of new and burdensome regulatory compliance obligations stemming from these long-dormant U.S. treaty obligations. The costs associated with bearing these looming regulatory burdens independently demonstrate the adverse effect the Proposed Rule, if finalized, would have on ATACH members like PharmaCann.

- ***Veterans and Medical Research:*** Opportunities for research in schedule III are more limited than if marijuana were to be descheduled, which would have a notable impact on ATACH member veterans and their ability to access plant-based medicine as an alternative to opioids. Some of ATACH’s members, including the nonprofit Hemp for Victory, actively advocate for research and access to medical cannabis for veterans. As a coalition with members like Hemp for Victory, ATACH is well-positioned to represent the interests of veterans who are seeking alternatives to opioids and who would benefit from the loosening of research protocols. Hemp for Victory’s prior petition calling for rescheduling of marijuana to schedules III, IV, or V and descheduling for these reasons is attached here as Exhibit E.

Hemp for Victory is already adversely affected and aggrieved by the Proposed Rule for another, independent reason—namely, DEA’s failure to respond to its petition seeking to reschedule or deschedule marijuana, challenging the constitutionality of certain statutory provisions bearing on the scope and substance of the Proposed Rule, and requesting that its petition be joined with the ongoing administrative action to reconsider marijuana’s schedule I classification in the wake of President Biden’s October 6, 2022, directive. The APA requires DEA to provide a timely response to such petitions and requests. *See* 5 U.S.C. § 555(b) (requiring agencies to act within a reasonable time). Because Hemp for Victory’s petition bears directly on the matters and issues at play in this rulemaking, raises

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fundamental statutory and constitutional issues, and requests, among other relief, precisely the remedy that the Proposed Rule contemplates, DEA's failure to acknowledge—much less resolve—the petition and Hemp for Victory's request for joinder adversely affects and aggrieves Hemp for Victory directly and concretely. It would therefore be especially improper to exclude Hemp for Victory from an administrative hearing related to the Proposed Rule.

- ***Abuse Potential, Medical Use in Treatment, Public Health Risks, and the Illicit Market:*** The public health risks of marijuana are far less significant than fentanyl, cocaine, or other controlled substances in schedule II. ATACH is prepared to present expert testimony on marijuana's abuse potential, currently accepted medical use in treatment in the United States, and the placement of marijuana on the CSA's schedules.¹² ATACH—as a representative of its members—seeks to fully participate in a hearing and formal rulemaking process to provide insights regarding the Proposed Rule's multifaceted effects on the state-legal, regulated marijuana marketplace. ATACH and its members desire a robust, regulated market for marijuana, and ATACH's participation would offer expert analysis of the risks the illicit market presents to cannabis businesses, consumers, and the public. The illicit market represents a significant issue raised by the Proposed Rule precisely because it is “not subject to any standards or oversight.” Proposed Rule at 44,606. ATACH would detail the current regulatory structures applicable to the state-legal marijuana marketplace and demonstrate that the variability of “product standards and safety requirements” are not nearly as “wide” as the Proposed Rule suggests. *See id.* Among other things, the Proposed Rule directly affects ATACH's work advocating for a robust, regulated marijuana marketplace. For example, ATACH's Board of Directors has created a standing committee that handles issues and advocacy regarding marijuana scheduling. The Proposed Rule will cause ATACH to expend time and resources to advocate on behalf of its members and to advance a robust, responsible marijuana marketplace. Michael Bronstein, President of ATACH, is leading national efforts to combat the unregulated intoxicating cannabinoid market and is prepared to testify on the public safety imperative of 26 U.S.C. § 280E relief for the state-regulated marketplace.
- ***Small and Minority-Owned Businesses and the Minority Cannabis Business Association:*** The Minority Cannabis Business Association (“MCBA”)—an ATACH member—advocates for the success of small and minority-owned businesses in the marijuana industry. The opportunities for many MCBA-member businesses, while essential, are also currently limited compared to what they would be if marijuana were descheduled. Significantly, criminal penalties will not change in schedule III, so MCBA members who are invested in criminal justice reform will see no change in sentencing protocols. As a result, MCBA and its members fall within the zone of interests and will be

¹² See Exhibit A (biographies of eight doctors prepared to testify on these issues).

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aggrieved by the Proposed Rule, if finalized, because it would not deschedule marijuana.¹³ MCBA also has equities in the outcome of this Proposed Rule because small businesses need the tax relief schedule III promises. They would therefore also be aggrieved by any final rule placing marijuana in schedule II or maintaining its schedule I placement. MCBA represents minority-owned and allied cannabis businesses, aspiring entrepreneurs, and supporters who share a vision of an equitable, just, and responsible cannabis industry. MCBA advocates for “social equity” in the cannabis industry that, among other things, empowers and supports the communities most affected by the War on Drugs. The Proposed Rule is silent as to equity considerations and how the Proposed Rule’s prospective controls may affect diverse communities. It is important for a hearing to address those issues given (i) the social equity issues inherent in the nation’s cannabis policies and (ii) the mandate of Executive Order 13,985 that “each agency must assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.” Executive Order No. 13,985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (Jan. 20, 2021). MCBA—as a member entity of ATACH—can provide testimony and evidence that can assist DEA in understanding the ramifications of its Proposed Rule on communities of color.¹⁴ Therefore, ATACH member MCBA has standing to participate in the agency’s upcoming hearing.

¹³ Throughout HHS’ evaluation, investigators compared the safety profile and abuse potential of cannabis versus several other controlled substances, which they referred to as “comparator drugs.” See Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (with enclosures) (Aug. 29, 2023) at PDF 8–9, <https://www.dropbox.com/scl/fi/pw3rfs9gm6lg80ij9tja6/2023-01171-Supplemental-Release-1.pdf?rlkey=v5atj0tcnxxhnszyzcwdcvvt&e=1&dl=0>. These comparator drugs not only included other schedule I substances like heroin but also included substances classified in lower schedules, such as benzodiazepines (schedule IV) and alcohol—which is unscheduled. Notably, on several occasions throughout its report, HHS concluded that cannabis poses a lower public health risk than these latter two substances. For instance, HHS concluded, “[t]he most notable conclusion from an evaluation of various epidemiological databases related to the medical outcomes from abuse of selected drugs is that for all measures that were evaluated from 2015 to 2020, the rank order of the comparators in terms of greatest adverse consequence typically places alcohol, heroin, and/or cocaine in the first or immediately subsequent positions, with marijuana in a lower place in the ranking.” *Id.* at PDF 46. HHS later reaffirmed this conclusion, acknowledging the following: “The risks to the public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological databases for emergency department (ED) visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths. . . . These evaluations demonstrate that there is consistency across databases, across substances, and over time that although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator drugs.” *Id.* at PDF 9. While HHS ultimately recommended transferring cannabis from schedule I to schedule III, the favorable safety profile of cannabis as compared to substances that are currently categorized in lower classifications—or, as in the case of alcohol, not scheduled at all—provides an argument in favor of descheduling cannabis entirely.

¹⁴ MCBA’s public comment, which details the issues MCBA is prepared to address at the hearing, is enclosed as an attachment to ATACH’s public comment submitted herewith. See Exhibit A.

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Under settled associational standing principles, MCBA's standing further reinforces ATACH's standing to participate as well. *See, e.g., Students for Fair Admissions, Inc.* 600 U.S. at 199 ("In cases . . . where the plaintiff is an organization, the standing requirements of Article III can be satisfied in two ways. Either the organization can claim that it suffered an injury in its own right or, alternatively, it can assert 'standing solely as the representative of its members.'" (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975))).

ATACH satisfies both of the standing tests reviewed in the Supreme Court's *Students for Fair Admissions* decision.

Under the first test, an organization may demonstrate standing by showing that it is injured in its own right. 600 U.S. at 199; *see also Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977). Of course, ATACH is not solely seeking to vindicate someone else's injuries or vicariously assert a member's damages. *See Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 400 (2024) (Thomas, J., concurring). Instead, and as described throughout this request, ATACH itself has suffered a concrete injury as a result of the Proposed Rule. *See TransUnion LLC v. Ramirez*, 594 U.S. 413, 442 (2021) (explaining that under Article III standing principles, generally, "no concrete harm" means "no standing"). Among other things, ATACH spends time, money, and other resources to advocate for a regulated, responsible marijuana marketplace, and the Proposed Rule necessarily imperils these expenditures. *See, e.g., American Anti-Vivisection Society v. United States Department of Agriculture*, 946 F.3d 615, 618–620 (D.C. Cir. 2020) (providing standing for group suing government agency that had devoted resources to providing guidance on handling, feeding, and housing birds); *Fair Housing Council of San Fernando Valley v. Roommate.com, LLC*, 666 F.3d 1216, 1219 (9th Cir. 2012) (providing standing where purported discrimination had frustrated the organization's purpose and caused it to divert resources); *see also Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (finding standing for an organization in its own right, reasoning that "concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests.").

Under the second test, associational standing is demonstrated when an organization can show "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Students for Fair Admissions*, 600 U.S. at 199 (quoting *Hunt*, 432 U.S. at 343). ATACH meets each of these three elements. As discussed above, Hemp for Victory and MCBA—among other ATACH member entities—have standing to participate, which, in turn, confers standing upon ATACH. The interests ATACH seeks to protect are germane to the organization's purpose: to foster a viable, safe, and regulated marijuana and hemp

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market with particular attention on public health and safety and consumer protection. ATACH can serve as a representative of its members in this proceeding, and the participation of individual member entities is not required.

- ***Practical Consequences:*** DOJ acknowledges that it is seeking comments on the “practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks.” Proposed Rule at 44,621. ATACH is prepared to provide expert testimony and documentary evidence on the implications of Section 280E of the Internal Revenue Code on state-sanctioned businesses and the public health and safety consequences of a final rule keeping marijuana in schedule I or transferring it to schedule II. This is particularly relevant to DEA’s questions about the “practical effects of the proposed rule” because a final rule transferring marijuana to schedule III would make Section 280E irrelevant as applied to the regulated industry, allowing it to compete with the untaxed, unregulated illicit marketplace more effectively. If the agency backtracks and decides that marijuana should remain in schedule I or be moved to schedule II, that decision would have significant negative impacts on ATACH, its members, and the safely regulated, age-gated state-level markets. While ATACH’s members currently suffer immense tax consequences as a result of 26 U.S.C. § 280E because of marijuana’s placement in schedule I, the practical consequences affect the health and safety of consumers and patients due to the regulated market’s inability to compete with the unregulated (illicit) market. ATACH’s members also face difficulty in conducting medical research and assisting veterans because of the schedule I designation. Economists retained by ATACH are prepared to testify about the implications of Section 280E relief on small and minority-owned cannabis businesses.¹⁵

Accordingly, ATACH—as a representative voice of its members—submits this filing to participate to the fullest extent permissible by law in the agency’s upcoming hearing. ATACH is also an “interested person” because the Proposed Rule would adversely affect and aggrieve ATACH and its members.

Put simply, the Proposed Rule, if finalized, would directly and adversely affect ATACH and its members. ATACH needs to show only administrative standing, rather than Article III standing, to participate in this administrative proceeding. *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (discussing a lower threshold required for “administrative standing” compared to Article III standing). Regardless, for all the reasons just described, ATACH has standing under both standards. Broad participation in agency proceedings and an expansive understanding of the term “interested person” are often necessary because the agency’s decision-making implicates public policy. *Id.*

¹⁵ ATACH is prepared to present testimony on this issue from Whitney Economics or FTI Consulting.

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E.

ATACH represents a coalition of active participants in and around the state-legal cannabis industry that are directly and adversely affected by the Proposed Rule. ATACH is thus uniquely situated to assist DEA's administrative decision-making at the upcoming hearing. ATACH and its members have extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated marijuana marketplace. DEA is actively seeking comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. ATACH is particularly well-suited to provide this insight, as it represents a broad coalition of interests, including (but not limited to) distributors, seed-to-sale technology providers, economic consultants, ingredient and garden care suppliers, financial service providers serving the cannabis industry, nonprofit researchers, and veterans groups, among other voices.

No basis exists to deny ATACH's participation at the upcoming hearing. In fact, none of the reasons courts have cited to deny a movant's participation in an administrative proceeding apply here. *See Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). Collecting cases, the D.C. Circuit noted that courts had denied participation when (i) other parties to the proceeding adequately represent the would-be participant's viewpoint, (ii) participation would broaden unduly the issues considered or obstruct or overburden the proceedings, or (iii) participation would fail to assist the agency's decision-making. *Id.*

First, no other participant in the rulemaking would adequately represent ATACH's viewpoint.¹⁶ ATACH has interests in the rulemaking proceedings distinct from those of DEA. As a broad coalition of member entities, ATACH represents an important and diverse group of interests that can speak to the practical consequences of rescheduling marijuana, the risk profile of marijuana and its favorable comparison to schedule I and II substances, and the risks the illicit market presents to cannabis businesses, among other topics.

Second, ATACH's participation would not unreasonably broaden the issues under consideration in the Proposed Rule or obstruct proceedings. DEA has sought information on the practical consequences of rescheduling. ATACH is prepared to provide that perspective. At the hearing, ATACH will abide by requirements and briefing applicable to other participants in the formal rulemaking procedure.

Third, ATACH's participation would benefit the agency's decision-making process if DEA were to grant a hearing. As noted above, ATACH's unique perspective would provide insight into (i) the impact of new marijuana-specific DEA controls on ATACH's members, (ii) medical research involving marijuana, particularly as it relates to veterans' access, (iii) abuse potential and public

¹⁶ While this filing is made without the knowledge of other participants in the potential ALJ hearing, ATACH provides a unique perspective that would not be cumulative to or adequately represented by other participants at the upcoming hearing regarding the Proposed Rule.

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health risks of marijuana, (iv) effects on members who are minority-owned and small businesses and whose communities have been impacted by the War on Drugs, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. ATACH is prepared to present expert testimony on these issues, as well as (inter alia) marijuana's currently accepted medical use in treatment in the United States, relevant international treaty obligations, and the placement of marijuana on the CSA's schedules.

For all these reasons, ATACH hereby requests the ability to participate in this rulemaking process to the fullest extent permissible by law and participate in the agency's upcoming hearing.

All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully yours,



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Enclosures

- Exhibit A: List of Expert Witnesses Prepared to Testify Regarding Marijuana's Abuse Potential and Currently Accepted Medical Use in Treatment in the United States
- Exhibit B: American Trade Association for Cannabis and Hemp, *DEA Public Comment Submission* (July 22, 2024)
- Exhibit C: *In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022)
- Exhibit D: OLC, *Questions Related to the Potential Rescheduling of Marijuana* (Apr. 11, 2024)
- Exhibit E: Hemp for Victory, *Petition to initiate rulemaking proceedings to deschedule marijuana or, alternatively, to transfer marijuana from schedule I to schedule III, IV, or V, and for joinder in pending rescheduling proceedings* (Nov. 15, 2023)

Exhibit A

ATACH is prepared to present expert testimony from any of the following doctors regarding marijuana's abuse potential, currently accepted medical use in treatment in the United States, and the placement of marijuana on the CSA's schedules:

1. **Dr. Duncan Mackie** is a DEA-licensed researcher, earning his PhD from the University of Iowa School of Pharmacy in medicinal and natural products chemistry. He is currently the director of pharmacology and experimental therapeutics at MedPharm Holdings, where he is responsible for all research and development activities surrounding MedPharm's long-standing interest in phytocannabinoids, neuropharmacology, and neurodegenerative diseases. He is an expert in drug discovery, pharmacology, medicinal chemistry, cellular/molecular biology, and models of human diseases. MedPharm is a member of ATACH.
2. **Dr. Malik Burnett** is an adjunct assistant professor in addiction medicine at the University of Maryland, a consultant for the Maryland Addiction Consultation Service, and medical director of several community opioid treatment programs in Maryland. He formerly served as the medical director for the Maryland Department of Health Center for Harm Reduction Services. Dr. Burnett holds an MD and PhD from Duke University and an MPH from Johns Hopkins University.
3. **Dr. Corey Burchman** is an assistant professor of anesthesiology at the Geisel School of Medicine at Dartmouth and a clinical anesthesiologist at Dartmouth-Hitchcock Medical Center. A 13-year Navy veteran, Dr. Burchman is a lecturer on the clinical effects of medicinal cannabinoids. He has been a practicing physician for over 35 years and is a fellowship-trained neuro-anesthesiologist and obstetrical anesthesiologist. Dr. Burchman previously served as the attending physician in the Department of Anesthesiology and served on the Acute Pain Service at the Dartmouth-Hitchcock Medical Center, practicing clinical anesthesia and interventional pain medicine. Previously, he was the medical director of the Post Anesthesia Care Unit and the Same Day Surgical Unit, as well as section chief of Neurosurgical Anesthesia.
4. **Dr. Robert Welch** is the director of the National Center for Cannabis Research and Education and research professor at the Research Institute for Pharmaceutical Sciences at the University of Mississippi. Dr. Welch holds a Doctor of Pharmacy degree from the University of Mississippi.
5. **Dr. Jordan Tishler** is the founder of the Association of Cannabinoid Specialists. He holds degrees from both Harvard College and Harvard Medical School, trained in internal medicine at the Brigham and Women's Hospital, and holds faculty positions at both Mass General Brigham and Harvard Medical School. Previously, Dr. Tishler spent many years as an emergency physician within the Veterans' Administration. Dr. Tishler is a national/international keynote speaker and author on medical applications of cannabinoids, including cannabinoid dosing paradigms, use of cannabinoids for pain management and opioid sparing, cannabinoids for behavioral health, and approaches to treatment of human sexual dysfunction using cannabinoids. He has numerous scientific

publications and has developed ongoing CME educational programs through the Association of Cannabinoid Specialists, Harvard Medical School, and other outlets.

6. **Dr. Deondra Asike** is a Board-Certified Anesthesiologist and Pain Medicine physician practicing at Johns Hopkins Hospital as a Clinical Associate in the Department of Anesthesiology and Critical Care Medicine. Dr. Asike is a veteran of the United States Air Force and has extensive experience in pain management in a variety of clinical settings. She is currently serving her second term on the Maryland Department of Health Prescription Drug Monitoring Program Advisory Board and chairs the Maryland Cannabis Public Health Advisory Council and The Maryland State Medical Society, MedChi Cannabis Committee. Previously, Dr. Asike was an Assistant Professor in the Department of Anesthesiology at the University of Maryland Shock Trauma Center. Dr. Asike holds a medical degree from Georgetown University School of Medicine. She completed her Anesthesiology residency training at the San Antonio Military Medical Center and Pain Medicine fellowship at the University of Maryland.
7. **Dr. Chris Hudulla** is a Ph.D. analytical chemist with more than 35 years of research experience in analytical chemistry. He is the Founder and Chief Scientific Officer of ProVerde Laboratories, Inc., a premier analytical research and testing facility for the regulated cannabis and hemp industries. Dr. Hudulla received his M.S. and Ph.D. from the University of California at Santa Barbara, and he has delivered presentations all over the world in his areas of expertise, including analytical testing, extraction, and research specific to cannabis and derivative products. He is active in numerous scientific organizations, contributing to efforts for the development and standardization of cannabis testing methodologies aimed at ensuring consumer safety.
8. **Dr. Andrew Coop** is professor and associate dean for graduate programs at the University of Maryland School of Pharmacy, has published more than 130 manuscripts and reviews, holds patents concerned with the chemistry and pharmacology of drugs with abuse liability, and has received funding from the National Institute on Drug Abuse. Dr. Coop is a recipient of the Joseph Cochin Young Investigator Award from the College on Problems of Drug Dependence, is a Fellow of both the College on Problems of Drug Dependence and the American Association of Pharmaceutical Scientists, received the James E. Wynn Memorial Award from the Chemistry Section of the American Association of Colleges of Pharmacy, and was named Maryland Chemist of the Year in 2019. Dr. Coop co-developed six courses in the groundbreaking Cannabis Science and Therapeutics MS program at the University of Maryland. He is sought for lectures on his expertise on the chemistry and pharmacology of drugs with abuse liability, has served as an expert witness in federal criminal trials, was recently appointed by Gov. Wes Moore to the newly formed Maryland Task Force on Responsible Use of Natural Psychedelic Substances, and testified to the U.S. Senate HELP Committee in February 2019 on approaches to treat pain during the opioid crisis, where he discussed the potential benefits of cannabis as an alternative to opioids.

Exhibit B



American Trade Association for Cannabis and Hemp

DEA Public Comment Submission

July 22, 2024

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Introduction

The American Trade Association for Cannabis and Hemp (“ATACH”) is a prominent national trade organization that promotes legal and regulatory frameworks for the marijuana and hemp industries in the United States.¹ In partnership with its member organizations and entities, ATACH concurs with the Biden Administration’s Notice of Proposed Rulemaking (“NPRM” or “Proposed Rule”)² and related scheduling assessment that places marijuana in schedule III of the Controlled Substances Act (“CSA”).

ATACH is particularly focused on public health and consumer safety. Founded in 2014 in response to the evolving legal and regulatory landscape of marijuana and hemp, ATACH works to influence public policy, promote the growth of the regulated industry, and enhance consumer protection safeguards and responsible business regulations. ATACH is based in Washington, D.C., and collaborates closely with state and federal lawmakers, regulatory agencies, researchers, standards organizations, accreditation bodies, and industry stakeholders to foster viable, safe, and regulated marijuana and hemp markets.

ATACH is formally recognized by the Internal Revenue Service as a 501(c)(6). Its member organizations and entities include researchers, laboratories, criminal justice reform advocates, investors, plant-touching companies, ancillary companies, and business associations—all with equities in this rulemaking. ATACH has standing as an “interested person,” as the new draft rule and subsequent scheduling determination by the Drug Enforcement Administration (“DEA”) will significantly impact its future sustainability as an industry organization and the operability of its member companies. Thus, ATACH has timely filed by U.S. mail a separate request (attached as Exhibit 1), pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, to participate in any administrative law judge (“ALJ”) hearing should the DEA Administrator grant one.

Among other things, ATACH has unique expertise and provides invaluable insights into (i) medical research involving marijuana, particularly as it relates to veterans’ access, (ii) the effects on minority-owned and small businesses whose communities have been negatively impacted by marijuana’s schedule I misclassification, (iii) the impact of new marijuana-specific DEA controls on ATACH’s member businesses and ancillary service providers, (iv) the abuse potential and public health risks of marijuana, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed to sale. ATACH is prepared to present expert testimony on these issues as well as, inter alia, marijuana’s currently accepted medical use (“CAMU”) in treatment in the United States, relevant international

¹ For purposes of this public comment submission, Perkins Coie LLP, and Porter, Wright, Morris, and Arthur LLP serve as legal and policy counsel for ATACH.

² Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

treaty obligations, and the appropriate placement of marijuana on schedule III of the CSA. ATACH's testimony would materially assist a DEA ALJ in preparing a sound and well-supported administrative decision. ATACH therefore submits the following public comments on behalf of the organization and its respective members as "interested person[s]."

The Proposed Rule represents a meaningful change in the federal government's characterization of marijuana and, in turn, has a significant impact on the nation's numerous state-regulated marijuana markets. Since Congress passed the CSA in 1970, marijuana has been classified as a schedule I controlled substance, subject to the most stringent controls and research limitations. Schedule I substances, according to DEA's current classification, have a "high potential for abuse" and lack "accepted medical use in treatment in the United States."³ Some examples of schedule I drugs are heroin, LSD, ecstasy, and peyote. The characterization of marijuana as a schedule I controlled substance was unsupported by medical science, law, factual evidence, sound public policy, and common sense in 1970—and remains so today.

This antiquated scheduling decision aligned marijuana with discernibly and demonstrably dangerous and addictive drugs that lack medical utility—some that serve as the primary drivers of the nation's drug overdose fatalities.⁴ The decision to control marijuana in the CSA alongside drugs such as heroin was not preceded by a rigorous scientific process like the one that DEA leads today. As a result of this outdated classification, U.S. citizens, primarily Black and brown citizens, have been imprisoned for possession and distribution of a largely innocuous plant; medical research and treatment have been stymied; precious federal resources have been squandered; and public safety imperatives have been compromised. Meaningfully, that obsolete and unsubstantiated schedule I designation is expected to change.

A recent recognition of scientific, medical, and 21st-century societal advances has contributed to the Biden Administration's decision to move forward with rulemaking to reclassify marijuana as a schedule III substance. Reclassifying marijuana to schedule III will have profound impacts on science, medicine, and research. It will also provide a lifeline to the highly regulated intrastate marijuana markets that protects the public health and safety of millions of American consumers through mandated security, manufacturing, testing, age gating, and inventory control protocols, among others, that don't exist in competing marijuana markets, including the illicit market and unregulated, synthetically-produced intoxicating hemp marketplaces.

³ 21 U.S.C. § 812(b)(1).

⁴ According to the National Institute on Drug Abuse ("NIDA"), synthetic opioids and heroin continued to drive overdose fatalities in 2022, with 81,806 deaths. Available at: [https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#:~:text=There%20were%20107%2C941%20drug%2Dinvolved,to%202022%20\(Figure%202\).](https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#:~:text=There%20were%20107%2C941%20drug%2Dinvolved,to%202022%20(Figure%202).)

This process began on October 6, 2022, when President Joseph R. Biden took a historic step in reforming the nation’s approach to marijuana regulation by calling out “our failed approach to marijuana” and asking the Department of Justice (“DOJ”) and the Department of Health and Human Services (“HHS”) to initiate an administrative process to review expeditiously the appropriateness of marijuana’s classification under federal law. Initiating this administrative process necessarily involved our nation’s leading health agencies, including the Food and Drug Administration (“FDA”), HHS, and the National Institute on Drug Abuse (“NIDA”). Before initiating proceedings to reschedule under the CSA, DEA gathered necessary data and requested a scientific and medical evaluation as well as a scheduling recommendation from HHS.

On August 29, 2023, HHS delivered over 250 pages of rigorous legal and scientific analysis summarizing its conclusion and recommendation. As detailed in the Proposed Rule, HHS conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III.⁵ Specifically, HHS concluded that marijuana has a lower potential for abuse than the other substances in schedules I and II, that marijuana has a CAMU, and that the abuse of marijuana may lead to moderate or low physical dependence or psychological dependence rather than the more severe consequences associated with schedule I and II substances.⁶

On May 21, 2024, DOJ issued a Proposed Rule, *Schedules of Controlled Substances: Rescheduling of Marijuana*.⁷ That decision made clear that DOJ, the parent agency of DEA, concurred with HHS’s findings, conclusions, and recommendations.

The Biden Administration has taken painstaking efforts during this rescheduling initiative, through both process and science, to get this right. While this rescheduling procedure was significantly shorter in duration than past scheduling decisions, this reflects the inefficiency of prior scheduling reviews and does not indicate that this process was flawed in any way. The current scheduling review was objectively more rigorous than any other scheduling review since the enactment of the CSA itself. The process involved all leading health and drug enforcement agencies, including FDA, NIDA, HHS, DEA, the State Department, and DOJ, as well as the Office of Management and Budget (“OMB”)—and the legal conclusions underpinning the decision were briefed, reviewed, and affirmed in an authoritative formal opinion by DOJ’s Office of Legal Counsel (“OLC”).⁸

⁵ 89 Fed. Reg. at 44,600.

⁶ *Id.* Thirty-eight states, the District of Columbia, and four territories have legalized the use of medical marijuana, allowing the use of the substance to treat certain health conditions, including chronic pain.

⁷ NPRM, 89 Fed. Reg. 44,597.

⁸ Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. ___, 4 (Apr. 11, 2024), <https://www.justice.gov/olc/media/1352141/dl?inline>.

These timely public comments support our previously filed request to participate in any ALJ hearing that the DEA Administrator might grant, are submitted in accordance with the NPRM,⁹ and are intended to offer scientific, medical, legal, and policy support for DOJ's decision to move forward with a rulemaking on the reclassification of marijuana as a schedule III drug under the CSA. This submission also supports the scientific determination by our leading health agencies that marijuana has a "currently accepted medical use in treatment in the United States" and an abuse potential less than those controlled substances listed in schedule II, including fentanyl.¹⁰

DEA will likely receive public comments from marijuana prohibitionists or others with political preconceptions or policy biases. These commenters will likely label botanical marijuana as "addictive" or "dangerous." But these views are antiquated, unfounded, and unsupported by research.¹¹ They also fail to credit the state-regulated marijuana industry that protects the very consumers those prohibitionists purport to safeguard. As DEA and DOJ review such comments, they must bear in mind the central role that the states play in protecting public health and safety generally and in overseeing the practice of medicine in particular. As the U.S. Supreme Court has emphasized, the CSA "presume[s] and rel[ies] upon a functioning medical profession regulated under the States' police powers,"¹² prohibits the federal government from making "anterior judgment[s]" about what constitutes accepted medicine or medical treatment,¹³ and "manifests no intent to regulate the practice of medicine generally."¹⁴

Our country's leading drug enforcement agency now has an opportunity to (1) place marijuana in a schedule that comports with modern science and has parity with drugs that have far less abuse potential than opioids and other drugs in schedule II, (2) recognize that marijuana has a CAMU, making its current designation scientifically improper and unlawful, and (3) support highly regulated intrastate programs that promote public safety, prevent youth use, mandate consumer protection safeguards, and benefit the economy.

⁹ Press Release, Dep't of Just., Justice Department Submits Proposed Regulation to Reschedule Marijuana (May 16, 2024), <https://www.justice.gov/opa/pr/justice-department-submits-proposed-regulation-reschedule-marijuana>.

¹⁰ See Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023), <https://s3.documentcloud.org/documents/24359427/hhs-marijuana-rescheduling.pdf> (enclosing *Basis for the Recommendation to Reschedule Marijuana Into Schedule III of the Controlled Substances Act*).

¹¹ Ben Adlin, 'No Evidence' That Marijuana Legalization For Adults Increases Youth Cannabis Use, New Research Published By American Medical Association Finds, MARIJUANA MOMENT (Apr. 24, 2024), <https://www.marijuanamoment.net/no-evidence-that-marijuana-legalization-for-adults-increases-youth-cannabis-use-new-research-published-by-american-medical-association-finds/>.

¹² *Gonzales v. Oregon*, 546 U.S. 243, 270 (2005).

¹³ *Id.* at 272.

¹⁴ *Id.* at 270.

While we address most of the questions DEA and DOJ posed below, particularly as they relate to abuse potential, we begin with common sense: marijuana does not belong in schedule I with drugs like heroin or even in schedule II with drugs like fentanyl.¹⁵ In this submission, we carefully analyze each significant scientific study over the past decade and reach the same conclusion as our leading health and law enforcement agencies—marijuana has a lower abuse potential than any controlled substance in schedules I and II.

In fact, marijuana has a lower abuse potential than nicotine—a drug that sits outside the CSA.¹⁶ HHS’s decision to compare the public health effects of alcohol to those of marijuana was particularly apt considering that alcohol and marijuana are among the two psychoactive substances most often consumed by Americans.¹⁷ As of this writing, 24 U.S. states now regulate the recreational use of marijuana for adults aged 21 and over more stringently, than alcohol.¹⁸ But marijuana use poses fewer and less severe risks than alcohol use, which is not included in the federal drug schedules.¹⁹ Marijuana also has far less abuse potential than fentanyl and other controlled substances currently listed in schedule II.²⁰

The nation’s leading scientists have even touted marijuana’s potential utility in our nation’s existential struggle against opioid use disorder and the overdose epidemic. According to a 2017 New England Journal of Medicine article authored by NIDA Director Dr. Nora Volkow and former National Institutes of Health Director Dr. Francis S. Collins, “[t]here is strong evidence of the efficacy of cannabinoids,

¹⁵ See The White House Briefing Room, *Statement from President Biden on Marijuana Reform*, (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/> (questioning the fact that “[f]ederal law currently classifies marijuana in Schedule I of the Controlled Substances Act, the classification meant for the most dangerous substances,” emphasizing that “[t]his is the same schedule as for heroin and LSD, and even higher than the classification of fentanyl and methamphetamine—the drugs that are driving our overdose epidemic,” and calling on “the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law”).

¹⁶ David J. Nutt et al., *Development of a rational scale to assess the harm of drugs of potential misuse*, 369 THE LANCET 1047–53 (Mar. 24, 2007), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(07\)60464-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60464-4/fulltext).

¹⁷ According to the 2022 National Survey on Drug Use and Health, 62.8% of those aged 12 and older have consumed alcohol in the past year, 22% have consumed cannabis, and 17.8% have consumed cigarettes. Substance Abuse and Mental Health Services Administration (“SAMHSA”), *Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health* (Nov. 13, 2023), <https://www.samhsa.gov/data/release/2022-national-survey-drug-use-and-health-nsduh-releases#detailed-tables>.

¹⁸ According to the National Conference of State Legislatures, 24 states, two U.S. territories, and the District of Columbia have now legalized marijuana for adults 21 and over. See Nat’l Conf. of State Legislatures, *Cannabis Overview* (updated June 20, 2024), <https://www.ncsl.org/civil-and-criminal-justice/cannabis-overview>.

¹⁹ Steve Fox et al., *Marijuana Is Safer: So why are we driving people to drink?* (2nd ed. 2013).

²⁰ See NPRM, 89 Fed. Reg. at 44,614 (discussing HHS’ recommendation on this point); see also *id.* at 44,618 (noting that heroin, cocaine, and fentanyl were considered “comparator substances controlled” under schedules I and II).

including tetrahydrocannabinol (THC), in treating pain.”²¹ They conclude that “[m]edications that target the endocannabinoid system ... could provide a powerful new tool” for “chronic pain management.” Put simply, marijuana is not a “gateway drug”; it’s an “exit drug.”²²

The abuse potential of substances can have serious consequences, and DOJ’s scheduling review and decision to proceed with this rulemaking come during a critical time in our nation’s history. Approximately 112,000 people died from drug overdoses last year,²³ and approximately 178,000 people die of alcohol abuse every year.²⁴ It is well established that alcohol—when consumed to excess in a short period—can cause a lethal overdose.²⁵ Alcohol is also a contributing factor to more than 1 in 6 opioid overdose deaths, according to NIDA.²⁶ Recent estimates put annual fatal overdoses attributable to fentanyl at 76,226 Americans.²⁷

By contrast, there is far less evidence to support the notion that marijuana use is to blame for frequent emergency department or substance abuse facility admissions.²⁸ Strikingly, DEA itself recognizes that zero deaths have been associated with marijuana overdose.²⁹ THC—the primary psychoactive ingredient in marijuana—cannot cause lethal overdose, regardless of the quantity ingested. Specifically, *The American Scientist* reported that the “ratio of effective dose to lethal dose” is 10 to 1 for alcohol, but such a ratio could not be calculated for marijuana.³⁰ In fact, several longitudinal studies have failed to link marijuana use to any increased

²¹ Nora D. Volkow & Francis S. Collins, *The Role of Science in addressing the Opioid Crisis*, 377 NEW ENG. J. OF MED. 391, 393 (July 27, 2017), <https://www.nejm.org/doi/pdf/10.1056/NEJMs1706626?articleTools=true>.

²² HHS officially abandoned the “gateway drug” hypothesis in 2016. 81 Fed. Reg. 53,767, 53,784 (Aug. 12, 2016) (concluding that “research does not support a direct causal relationship between regular marijuana use and other illicit drug use” and emphasizing that “[l]ittle evidence supports the hypothesis that initiation of marijuana use leads to an abuse disorder with other illicit substances”).

²³ Brian Mann, et al., *In 2023 fentanyl overdoses ravaged the U.S. and fueled a new culture war fight*, NPR (Dec. 28, 2023), <https://www.npr.org/2023/12/28/1220881380/overdose-fentanyl-drugs-addiction>.

²⁴ *Alcohol-Related Emergencies and Deaths in the United States*, NAT’L INST. ON ALCOHOL ABUSE & ALCOHOLISM (2023, as updated 2024), <https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics/alcohol-related-emergencies-and-deaths-united-states>.

²⁵ Marissa B. Esser et al., *Deaths from Excessive Alcohol Use — United States, 2016–2021*, 73 MORBIDITY & MORTALITY WEEKLY REP. 154–61 (Feb. 29, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/mm7308a1.htm>.

²⁶ NIH, NAT’L INST. ON ALCOHOL ABUSE AND ALCOHOLISM, *Alcohol-Related Emergencies and Deaths in the United States* (2024), <https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics/alcohol-related-emergencies-and-deaths-united-states>.

²⁷ Press Release, CDC National Center for Health Statistics, U.S. Overdose Deaths Decrease in 2023, First Time Since 2018 (May 15, 2024), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.htm.

²⁸ See NPRM, 89 Fed. Reg. at 44,601 (“HHS also concluded that public-health risks posed by marijuana are lower compared to those posed by other drugs of abuse....”).

²⁹ DEA, *Drug Fact Sheet Marijuana/Cannabis*, (April 2020) https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf.

³⁰ Robert S. Gable, *The Toxicity of Recreational Drugs*, 94 AM. SCIENTIST 206 (May/June 2006), <https://www.americanscientist.org/article/the-toxicity-of-recreational-drugs>.

risk of premature death³¹—including deaths due to lung³² and other tobacco-related cancers.³³

Notably, it is not only the act of consuming alcohol that can adversely impact the health of the user. In fact, ceasing one's use of alcohol can pose serious health risks in certain circumstances. For longtime habitual abusers of alcohol, withdrawing from the drug may trigger delirium tremens—a condition characterized by body tremors, hallucinations, and even cardiovascular collapse.³⁴ By comparison, marijuana-associated withdrawal is typically characterized by feelings of anxiety, irritability, and disturbed sleep, among other far less harmful symptoms.³⁵ These symptoms are typically short-lived and are not clinically significant for most people.³⁶

HHS found that marijuana compares favorably to the public health risks of substances in schedules I and II, such as heroin (schedule I), cocaine (schedule II), and fentanyl (schedule II).³⁷ According to data from the Centers for Disease Control and Prevention ("CDC"),³⁸ heroin, cocaine, and fentanyl are responsible for tens of thousands of fatalities annually. In fact, DEA has launched a public awareness campaign that even "One Pill" of fentanyl "Can Kill," noting that 2 milligrams of

³¹ See, e.g., S. Andréasson & P. Allebeck, *Cannabis and mortality among young men: a longitudinal study of Swedish conscripts*, 18 SCAND. J. OF SOC. MED. 9–15 (1990), <https://pubmed.ncbi.nlm.nih.gov/2320981/> ("After controlling for social background variables in a multivariate model, no excess mortality was found."); S. Sidney et al., *Marijuana use and mortality*, 87 AM. J. OF PUB. HEALTH 585–90 (Apr. 1997), <https://pubmed.ncbi.nlm.nih.gov/9146436/> ("Marijuana use in a prepaid health care-based study cohort had little effect on non-AIDS mortality in men and on total mortality in women."); Edison Manrique-Garcia et al., *Cannabis, Psychosis, and Mortality: A Cohort Study of 50,373 Swedish Men*, 173 AM. J. OF PSYCHIATRY 790–98 (Aug. 1, 2016), <https://pubmed.ncbi.nlm.nih.gov/27102239/> ("The authors found an excess mortality among subjects with psychotic disorders, but the level [of excess mortality] did not differ between those with a history of cannabis use and those without such a history.").

³² Donald P. Tashkin & Wan-Cheng Tan, *Inhaled Marijuana and the Lung*, 10 J. OF ALLERGY & CLINICAL IMMUNOLOGY 2822–29 (Nov. 2022), [https://www.jaci-inpractice.org/article/S2213-2198\(22\)00495-0/abstract](https://www.jaci-inpractice.org/article/S2213-2198(22)00495-0/abstract) ("On balance, the available evidence at least thus far does not suggest that marijuana smoking poses an increased risk of lung cancer when adjustments are made for concomitant tobacco smoking.").

³³ S. Sidney et al., *Marijuana use and cancer incidence (California, United States)*, 8 CANCER CAUSES CONTROL 722–28 (Sept. 1997), <https://pubmed.ncbi.nlm.nih.gov/9328194/> ("Marijuana use also was not associated with tobacco-related cancers or with cancer of the following sites: colorectal, lung, melanoma, prostate, breast, cervix.").

³⁴ Shannon Toohey, *Delirium Tremens (DTs)*, MEDSCAPE (Aug. 4, 2021), <https://emedicine.medscape.com/article/166032-overview>.

³⁵ Jason P. Connor et al., *Clinical management of cannabis withdrawal*, 117 ADDICTION 2075–95 (Jan. 2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9110555/>.

³⁶ U. W. Preuss et al. *Cannabis withdrawal severity and short-term course among cannabis-dependent adolescent and young adult inpatients*, 106 DRUG & ALCOHOL DEPENDENCE 133–41 (Jan. 2010), <https://www.sciencedirect.com/science/article/abs/pii/S0376871609003275?via%3Dihub>.

³⁷ See NPRM, 89 Fed. Reg. at 44,614 (discussing HHS' recommendation on this point); see also *id.* at 44,618 (noting that heroin, cocaine, and fentanyl were considered "comparator substances controlled" under schedules I and II).

³⁸ CDC Nat'l Ctr. for Health Statistics, *Provisional Drug Overdose Death Counts* (updated Feb. 15, 2023), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

fentanyl (an amount smaller than a pencil tip) can be deadly.³⁹ Given the deadly nature of fentanyl—a schedule II substance—the risk profile of marijuana stands in stark relief. As noted above, DEA itself recognizes that zero deaths have been associated with marijuana overdose.⁴⁰

While DOJ's OLC has determined that DEA must accord "significant deference" to HHS's scientific and medical determinations throughout the scheduling process,⁴¹ DEA has always inherently relied upon HHS's scientific and scheduling recommendations to reach a conclusion regarding a substance's abuse potential. Indeed, having reviewed every scheduling decision DEA and its predecessor agency have ever made under the CSA, we can certify that neither agency has *ever* overruled an HHS determination regarding a substance's abuse potential.⁴² Accordingly, now that HHS has found that marijuana has a lower abuse potential than those controlled substances in schedules I and II, DEA should do what it has literally *always* done in the past: accept HHS's well-reasoned judgment and recommendation.

In addition to its low abuse potential, marijuana has a CAMU that supports its rescheduling from schedule I to schedule III. DOJ's NPRM makes clear that the Attorney General agrees with our leading health agencies' scientific determination that marijuana has a CAMU. A recent study also reported that a majority of medical professionals acknowledge marijuana's medical uses and support removing it from schedule I.⁴³

As we summarize in our comments below, DOJ's decision confirmed that the 38 highly regulated intrastate medical markets recommending marijuana for more than six million patients suffering from a variety of ailments is evidence of "currently accepted medical use in treatment in the United States."⁴⁴ The decision further confirms that marijuana's abuse potential is less than deadly heroin, fentanyl, cocaine, and other controlled substances in schedules I and II.⁴⁵

In its July 17, 2023, submission to DEA, HHS updated its analysis of marijuana's CAMU for purposes of the CSA. As part of its analysis, HHS updated its test for CAMU and included consideration of (1) whether there is widespread current experience with medical use of the substance in the United States by licensed health care practitioners ("HCPs") operating in accordance with implemented

³⁹ DEA, *One Pill/Can Kill*, <https://www.dea.gov/onepill>.

⁴⁰ *Drug Fact Sheet*, *supra* note 29.

⁴¹ 48 Op. O.L.C. ___, *supra* note 8.

⁴² A list of those decisions with their respective Federal Register citations is available at <https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.

⁴³ Jared M. Weisman & Marcus Rodríguez, *A systematic review of medical students' and professionals' attitudes and knowledge regarding medical cannabis*, 3 J. CANNABIS RSCH. 47 (Oct. 12, 2021), <https://pubmed.ncbi.nlm.nih.gov/34641976>.

⁴⁴ See NPRM, 89 Fed. Reg. at 44,619.

⁴⁵ *Id.* at 44,620.

state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine, and (2) whether there is scientific support for at least one of these medical uses.⁴⁶

HHS's CAMU analysis in Part (1) of this approach was supported by the following non-dispositive factors: (a) whether a substantial number of HCPs have gained clinical experience with at least one specific medical use of the substance under existing and implemented state-authorized programs, (b) whether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance, and (c) whether an HCP's clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer-term toxicities and potential harms of the substance when used under medical supervision.⁴⁷

Part (2) of this updated standard for CAMU recognized that approval from FDA of a pharmaceutical drug, following clinical trials and premarket review, and satisfying DEA's five-part test modeled on that FDA standard are no longer the only paths to determining CAMU. Instead, FDA indicated that Part (2) of the CAMU test "evaluates whether there exists some credible scientific support for at least one of the medical conditions for which the Part (1) test is satisfied."⁴⁸ The nation's leading health agency went on to indicate that "FDA's evaluation in Part (2) is not meant to be, nor is it, a determination of safety and efficacy that meets the Federal Food, Drug, and Cosmetic Act's drug approval standard for new human or animal drugs. Rather, the two-part test is to determine whether a substance, in this case marijuana, has a CAMU for purposes of drug scheduling recommendations and placement in a drug schedule consistent with criteria set forth in 21 U.S.C. 812(b)."⁴⁹ DOJ's OLC issued a memorandum finding that the updated HHS test was not only lawful but also sufficient to establish that a drug has a CAMU.⁵⁰ Unless overruled by the Attorney General or the President, OLC's decisions are binding on the entire Executive Branch, including DEA.⁵¹

To evaluate whether marijuana met one or more of the three Part (1) factors, HHS assessed currently available data from states and other federal agencies on the medical use of marijuana in the United States. HHS confirmed that more than 30,000 HCPs across the United States are authorized to recommend the medical use of

⁴⁶ See Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, Re: Part 1 Analysis at 1 (July 17, 2023) ("HHS Part 1 Analysis Memo").

⁴⁷ See *id.* at 2.

⁴⁸ Ctr. for Drug Evaluation & Rsch., FDA, Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act at 3 (Aug. 28, 2023) ("HHS Part 2 Analysis Memo").

⁴⁹ HHS Basis for Rec. at 24.

⁵⁰ 48 Op. O.L.C. ___, *supra* note 8.

⁵¹ *Principles to Guide the Office of Legal Counsel*, https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2927&context=faculty_scholarship

marijuana to more than 6,000,000 registered patients for at least 15 medical conditions, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States.⁵² HHS specifically found that “the data support that a substantial number of HCPs have gained clinical experience with at least one specific medical use of marijuana under state authorized programs.”⁵³ HHS also concluded that a substantial number of regulatory entities recognize at least one specific medical use of the substance.⁵⁴ Finally, HHS determined that HCPs’ clinical experience recommending marijuana for various medical conditions is of sufficient extent and duration to help evaluate potential clinical uses.⁵⁵

Following the HHS review, FDA determined in Part (2) of the analysis that there exists “some credible scientific support for the use of marijuana” for at least one medical condition identified by HHS.⁵⁶ In making this determination, FDA conducted Part (2) of the test for seven indications. It based its analysis partially on HHS’s review in Part (1) and partially on its own assessment of the “landscape in which marijuana is currently used medically, including information from state-authorized programs on how and to what extent marijuana is being utilized for medical purposes.”⁵⁷ The seven indications examined were anorexia, anxiety, epilepsy, inflammatory bowel disease, nausea and vomiting, pain, and post-traumatic stress disorder.⁵⁸

FDA’s evaluation under Part (2) of the CAMU test was based on “systematic reviews of studies investigating the safety and effectiveness of marijuana, relevant professional societies’ position statements, data from state medical marijuana programs and U.S. national surveys, and the labeling of FDA-approved products relevant to the analysis.”⁵⁹ FDA concluded that the largest evidence base for effectiveness exists for marijuana use with the “pain indication.”⁶⁰ In addition, FDA found credible scientific support for anorexia related to a medical condition and for nausea and vomiting.⁶¹ Notably, FDA did not “identif[y] any safety concerns that

⁵² HHS Basis for Rec. at 24.

⁵³ HHS Part 1 Analysis Memo at 3.

⁵⁴ *Id.* at 3–5.

⁵⁵ *Id.* at 5.

⁵⁶ HHS Part 2 Analysis Memo at 7.

⁵⁷ *Id.* at 4.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 5.

⁶¹ HHS Basis for Rec. at 28.

would preclude the use of marijuana in the indications for which there exists some credible scientific support for its therapeutic benefit.”⁶²

In the epidemiological analyses regarding the prevalence of marijuana *abuse*, evaluations included comparators such as heroin (schedule I), fentanyl (schedule II), oxycodone (schedule II), hydrocodone (schedule II), cocaine (schedule II), ketamine (schedule III), benzodiazepines (schedule IV), zolpidem (schedule IV), tramadol (schedule IV), and alcohol (not controlled).⁶³ After assessing all available preclinical, clinical, and epidemiological data, FDA found that marijuana had less abuse potential than controlled substances in schedules I and II and recommended that marijuana be rescheduled from schedule I into schedule III of the CSA.⁶⁴ While using schedule II substances may lead to severe psychological or physical dependence, schedule III drugs are classified as having a lower potential for abuse than the substances in schedules I and II and a CAMU.

As detailed in the Proposed Rule, HHS conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III.⁶⁵ Specifically, HHS concluded that marijuana has a potential for abuse less than other substances in schedules I and II, that marijuana has a CAMU, and that the abuse of marijuana may lead only to moderate or low physical dependence or psychological dependence.⁶⁶ In addition, the legalization of medical marijuana in 38 states, the District of Columbia, and four territories supports the finding that marijuana has a CAMU.⁶⁷

OMB has also made a specific request for economic data, concluding that “this action may have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act., 5 U.S.C. 601.” In addition to the science and public health and safety imperative supporting a schedule III determination, the scale and economic impacts of the nation’s state-regulated marijuana industry cannot be discounted. The state-regulated industry generated an estimated \$33 billion in sales revenue in 2022 and is projected to generate over \$71 billion by 2030.⁶⁸ A 2024 report estimated that the state-regulated marijuana industry currently supports

⁶² *Id.* at 26.

⁶³ NPRM, 89 Fed. Reg. at 44,618.

⁶⁴ *Id.* at 44,616.

⁶⁵ *Id.* at 44,615.

⁶⁶ *Id.*

⁶⁷ *Id.* at 44,617.

⁶⁸ Press Release, BDSA, BDSA Reports Global Legal Cannabis Sales to Reach \$59.6 Billion in 2027 (Feb. 22, 2023), <https://www.globenewswire.com/news-release/2023/02/22/2613335/0/en/BDSA-Reports-Global-Legal-Cannabis-Sales-to-Reach-59-6-Billion-in-2027.html>.

more than 440,445 full-time equivalent jobs.⁶⁹ To address the Proposed Rule's economic and operational impacts on minority-owned marijuana businesses in the United States more specifically, ATACH also adopts the public comment of its association member and partner, the Minority Cannabis Business Association, and its president, Tahir Johnson, and attaches their submission here as Exhibit 2.⁷⁰

Consumer demand for marijuana products is also not likely to wane. A recent Pew Research Center poll highlights the overwhelming popularity of marijuana.⁷¹ Polls indicate 88% of Americans agree that marijuana should be legal for medical or recreational use.⁷² As of November 2023, 7 in 10 Americans back a complete end to marijuana prohibition, according to a Gallup poll indicating the highest level of support for this issue since the firm started tracking in 1969.⁷³ With 38 state medical markets and 24 adult-use markets fully operational, there is no turning back the clock.⁷⁴ The only question for policymakers is whether to help the state-regulated market keep the public safe or allow the illicit market and the unregulated synthetic intoxicating hemp-derived cannabinoid ("IHDC") market to proliferate. Rescheduling marijuana to schedule III is the only logical answer.⁷⁵

While federal law has prohibited the "trafficking" of marijuana for more than 50 years, the regulatory landscape at the state level has changed dramatically over the past decade.⁷⁶ In each state that has legalized marijuana, there are now regulators tasked with drafting and implementing laws and regulations intended to protect consumers, prevent diversion, prevent access and marketing to minors, and collect taxes. The Cannabis Regulators Association ("CANNRA") is led by a public

⁶⁹ Ben Adlin, *The Legal Marijuana Industry Now Supports More Than 440,000 Full-Time Jobs, Up 5% From Last Year, Report Finds*, MARIJUANA MOMENT (Apr. 10, 2024), <https://www.marijuanamoment.net/the-legal-marijuana-industry-now-supports-more-than-440000-full-time-jobs-up-5-from-last-year-report-finds/>.

⁷⁰ Tahir Johnson also serves as CEO and owner of Simply Pure, a New Jersey dispensary.

⁷¹ Ted Van Green, *Americans overwhelmingly say marijuana should be legal for medical or recreational use*, PEW RSCH. CTR. (Nov. 22, 2022), <https://www.pewresearch.org/fact-tank/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use>.

⁷² *Id.*

⁷³ Kyle Jaeger, *Support For Marijuana Legalization Reaches Record High Of 70 Percent, Including Strong Majority Of Republicans*, Gallup Poll Shows, MARIJUANA MOMENT (Nov. 8, 2023), <https://www.marijuanamoment.net/support-for-marijuana-legalization-reaches-record-high-of-70-percent-including-strong-majority-of-republicans-gallup-poll-shows/>.

⁷⁴ To our knowledge, DOJ has not engaged in any meaningful enforcement against companies that comply with state law and do not violate the eight federal priorities. However, the NPRM notes that treaties compliance may dictate that new DEA controls are appropriate. A revised Cole (Monaco) Memorandum would go a long way toward stabilizing the state-regulated marketplace by offering assurances that companies abiding by state regulatory regimes can continue to operate in schedule III without fear of federal enforcement so long as they abide by the guidelines set by DOJ.

⁷⁵ While ATACH and the Coalition for Cannabis Scheduling Reform ("CCSR") believe that marijuana should be descheduled, the administrative process could not have yielded such a result.

⁷⁶ New Frontier Data, *2023 U.S. Cannabis Report: Market Updates & Projections* at 3 (Mar. 2023), <https://info.newfrontierdata.com/2023-us-cannabis-report> (finding 39 states (inclusive of D.C.) operating legal medical marijuana markets and 22 states (inclusive of D.C.) with legalized adult-use markets).

health expert, and its board members consist of regulators with prior disciplines in law, public policy, and law enforcement.⁷⁷ Marijuana firms in the highly regulated intrastate marketplace are subject to rigorous state regulations that set criteria for security and surveillance infrastructure, packaging and labeling, lab testing, dosage limits, per-package limits, inventory controls, and age verification, among many other consumer protections. The illicit market and the synthetic IHDC market share none of these protections.

With marijuana in schedule I, the highly regulated intrastate marijuana industry has faced serious financial challenges and stiff competition from the illicit marijuana market and the unregulated synthetic IHDC market—both of which sell products in interstate commerce.

Because of questionable interpretations of the 2018 Farm Bill, synthetic IHDC products are largely unregulated and commonly available without age restrictions or adequate labeling requirements.⁷⁸ A recent medical research study concluded that the pervasiveness of unregulated synthetic IHDC products imperils public health.⁷⁹ Many manufacturers of synthetic IHDC products operate unregulated, selling products that far exceed the potency levels of marijuana-derived cannabinoids allowable in the state-regulated marketplace.⁸⁰ Synthetic IHDC products are particularly dangerous as they do not require age verification, lab testing for heavy metals and other impurities, or consistent packaging and labeling—and the majority of synthetic IHDC product manufacturers are selling their goods in interstate commerce. Due to the lack of regulatory oversight and age gating of sales, an FDA evaluation of poison control center calls from exposure to delta-8

⁷⁷ 2023-2024 Executive Board, CANNRA, <https://www.cann-ra.org/leadership> (last accessed July 15, 2024).

⁷⁸ Rob Mentzer, *A loophole in federal marijuana law has led to the creation of new THC product*, NPR (Jan. 4, 2022), <https://www.npr.org/2022/01/04/1070338052/a-loophole-in-federal-marijuana-law-has-led-to-the-creation-of-new-thc-product>.

⁷⁹ Jennifer M. Whitehill, Kelly E. Dunn, & Renee M. Johnson, *The Public Health Challenge of Δ8-THC and Derived Psychoactive Cannabis Products*, 331 JAMA 834–36 (Mar. 12, 2024), <https://jamanetwork.com/journals/jama/article-abstract/2816109>; Alyssa F. Harlow, Richard A. Miech & Adam M. Leventhal, *Adolescent Δ8-THC and Marijuana Use in the US*, 331 JAMA 861–65 (Mar. 12, 2024), <https://jamanetwork.com/journals/jama/article-abstract/2816083>.

⁸⁰ Ben Adlin, *21 State Attorneys General Push Congress To Regulate Intoxicating Hemp Products*, MARIJUANA MOMENT (Mar. 20, 2024), <https://www.marijuanamoment.net/21-state-attorneys-general-push-congress-to-regulate-intoxicating-hemp-products/> (“[T]he reality is that [the 2018 Farm Bill] has unleashed on our states a flood of products that are nothing less than a potent form of cannabis, often in candy form that is made attractive to youth and children—with staggering levels of potency, no regulation, no oversight, and a limited ability for our offices to rein them in.”); Stephanie Zimmermann & Tom Schuba, *Hemp products often mislabeled, posing potential danger to consumers, Chicago researcher finds*, CHI. SUN-TIMES, Mar. 20, 2024, <https://chicago.suntimes.com/the-watchdogs/2024/03/20/hemp-cbd-edibles-weed-thc-delta8-danger-uic-bash> (“A new study found [IHDC] products, typically sold at smoke shops and gas stations, often have a higher potency than advertised and fail to mention which psychoactive substances they contain, adding a new level of urgency to lawmakers’ efforts to regulate an industry with few guardrails.”); Press Release, Minnesota Department of Health cautions consumers about illegal high-dose THC products (Dec. 13, 2023), <https://www.health.state.mn.us/news/pressrel/2023/thc121323.html> (“Illegal, high-dose hemp-derived products may contain hundreds of milligrams of THC per serving, and with multiple servings in a package, this can add up to thousands of milligrams of THC – far above the legal limit[.]”).

tetrahydrocannabinol (“delta-8 THC”) found that 41% of the incidents involved pediatric patients less than 18 years of age.⁸¹ The synthetic IHDC product industry threatens public health and safety throughout the country, particularly for minors, as does the illicit marijuana marketplace.

In a federally funded study released on March 12, 2024, researchers found that teen use of unregulated hemp-derived delta-8 THC is lower in states where state-regulated marijuana programs exist.⁸² Along with this scientific study, the well-regarded *Journal of the American Medical Association* (“JAMA”) published an editorial about the new conclusions, opining that the “weak regulatory infrastructure for delta-8 THC has led to manufacturing, advertising, and sales practices that are inconsistent with public health and safety.”⁸³ The authors further remarked that this “unintended consequence of the Farm Bill . . . contrasts sharply with legalization of medical or adult-use cannabis.” Thus, it makes sense that the federal government is taking steps to support the well-regulated intrastate programs. Our leading health agencies agree, with HHS and FDA lamenting the fact that adverse events related to synthetic IHDCs are skewing the data the agency received for assessing marijuana’s abuse potential.⁸⁴

Additionally, due to draconian tax policies attributable to 26 USC § 280E of the Internal Revenue Code (“IRC”), state-regulated marijuana companies have been paying up to an effective 52% federal tax rate.⁸⁵ Moving marijuana to schedule III will transform the highly regulated intrastate marijuana marketplace, helping to sustain the state-regulated businesses that displace illicit sales. Among other benefits, state-regulated marijuana businesses will be able to write off ordinary business expenditures.

Under current law, ordinary business deductions are disallowed if a marijuana firm is “trafficking in a schedule I or II substance.” Upon rescheduling to schedule III, this provision of the federal tax code will no longer apply. Rescheduling to schedule III will therefore remove the myriad impediments to sustainability that the IRC currently imposes on the state-regulated marketplace. The illicit market pays no taxes at all, and hemp-derived products that test below 0.3% delta-9 tetrahydrocannabinol (“delta-9 THC”) on a dry weight basis are arguably not subject to § 280E because the industry is not “trafficking” in a schedule I or schedule II controlled substance. Eliminating the strictures of § 280E is sound public policy and

⁸¹ FDA, “5 Things to Know About Delta-8 Tetrahydrocannabinol – Delta-8 THC” (May 4, 2022), <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>.

⁸² Harlow et al., *supra* note 79.

⁸³ Whitehill et al., *supra* note 79.

⁸⁴ See HHS Basis for Rec. at 1–2.

⁸⁵ Exhibit 2 at 3–4.

will safeguard the well-regulated intrastate industry that protects public health and the safety of consumers.

Thus, in addition to following the science, there is a public health and safety imperative to reschedule marijuana to schedule III. If the rule to reclassify is not finalized in a timely manner, the well-regulated intrastate industry will likely face insurmountable headwinds from unregulated synthetic IHDC products and the illicit market operating in interstate commerce without consumer protection-focused guardrails.⁸⁶ The results could be catastrophic for the public health and safety of unwitting American consumers.

It is against this backdrop that we submit our public comments as “interested person[s].”⁸⁷

Potential for Abuse

I. HHS Correctly Concluded That Marijuana Has an Abuse Potential Less Than Substances in Schedules I and II.

In 2022-2023, HHS (through FDA) engaged in a rigorous, comprehensive medical and scientific analysis of marijuana based on available data, including the substance’s abuse potential. This review, which included a thorough 8-Factor Analysis (“8FA”), culminated in the recommendation to reschedule marijuana from schedule I to schedule III. When evaluating Factor 1 of the 8FA (abuse potential), and consistent with Congress’s legislative intent behind the CSA, HHS analyzed considerable data related to marijuana’s abuse potential according to the following established criteria for whether a particular drug or substance has potential for abuse:

- (1) there is evidence that individuals are consuming the substance in amounts sufficient to create a hazard to their health or to the safety of others;
- (2) there is significant diversion of the drug from legitimate drug channels;
- (3) individuals are consuming the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances; and

⁸⁶ Ben Adlin, *Search Interest In Delta-8 THC Nearly Twice As High In States Without Legal Marijuana, Study Finds*, MARIJUANA MOMENT (Feb. 12, 2024), <https://www.marijuanamoment.net/search-interest-in-delta-8-thc-nearly-twice-as-high-in-states-without-legal-marijuana-study-finds/>; Kyle Jaeger, *States That Ban Marijuana May ‘Unintentionally Promote’ Unregulated Delta-8 THC Products, Federally Funded Study Finds*, MARIJUANA MOMENT (Dec. 13, 2023), <https://www.marijuanamoment.net/states-that-ban-marijuana-may-unintentionally-promote-unregulated-delta-8-thc-products-federally-funded-study-finds/>.

⁸⁷ 21 C.F.R. § 1300.01 (defining “interested person” for purposes of the CSA).

(4) the substance is so related in its action to a substance already listed as having potential for abuse to make it likely that it will have the same potential for abuse as such substance thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.⁸⁸

Within these criteria, HHS has significant latitude in determining a substance's abuse potential. For example, the scientific evaluation of the relative abuse potential of a substance can include consideration of epidemiological data related to "abuse of the substance regarding its pattern and duration of use, as well as the risk it presents to the public health."⁸⁹ Note, this approach, in terms of source reliance, is consistent with FDA Guidance for Industry discussing abuse potential assessments.⁹⁰ Epidemiological data featured prominently in HHS's 2023 Analysis, and HHS focused largely on new epidemiological data related to abuse of marijuana in the years since the agency's 2015 Analysis.⁹¹ The epidemiological analyses regarding prevalence of marijuana abuse and associated harms included comparators such as heroin (schedule I), fentanyl (schedule II), oxycodone (schedule II), hydrocodone (schedule II), cocaine (schedule II), ketamine (schedule III), benzodiazepines (schedule IV), zolpidem (schedule IV), tramadol (schedule IV), and alcohol (FDA Office of Surveillance and Epidemiology, 2023).⁹² As HHS stated in the 2023 Analysis and in its prior analysis of marijuana's abuse potential in its 2015 Analysis, "[d]etermining the abuse potential of a substance is complex with many dimensions, and no single test or assessment provides a complete characterization. Thus, no single measure of abuse potential is ideal."⁹³

⁸⁸ HHS Basis for Rec. at 6. This test is derived from the legislative history of the CSA, which suggests using these criteria in determining whether a particular drug or substance has a potential for abuse. *See* COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970, H.R. REP. NO. 91-1444, (1970) *reprinted in* 1970 U.S.C.C.A.N. 4566, 4603.

⁸⁹ HHS Basis for Rec. at 6; Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688, 53,690 (Aug. 12, 2016) ("2016 Proposed Rule") (HHS's recommendation to DEA is dated June 25, 2015, hereinafter "2015 Analysis"). Such analysis can include consideration of other elements such as chemistry, receptor binding, behavioral effects indicating that the substance is rewarding or is similar to another substance controlled under the CSA, pharmacokinetics, behavioral effects indicating that the substance produces physical or psychic dependence.

⁹⁰ FDA GUIDANCE FOR INDUSTRY, ASSESSMENT OF ABUSE POTENTIAL OF DRUGS, at 32 (Jan. 2017), <https://www.fda.gov/media/116739/download>.

⁹¹ HHS Basis for Rec. at 5.

⁹² Note, each individual epidemiological database evaluated a specific group of drugs and not every comparator was evaluated under each database.

⁹³ HHS Basis for Rec. at 6; 2016 Proposed Rule at 53,690.

Based on an abuse potential analysis that hewed to the CSA legislative history criteria for determining abuse potential, HHS determined that epidemiological data indicate that marijuana has the potential for creating hazards to the health of the user and to the safety of the community. However, as a relative finding on abuse liability, when comparing marijuana to the comparator substances in the epidemiological databases that permit some or all of these comparisons (i.e., heroin, oxycodone, ketamine, benzodiazepines, alcohol, etc.), “marijuana is not typically among the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder.”⁹⁴ What is particularly noteworthy is that there are marijuana and marijuana-derived products available to consumers containing extremely high levels of delta-9 THC, and thus, the epidemiological data relied upon by HHS in its analysis encompasses outcomes from individuals using products with low to high doses of delta-9 THC. And still, the data shows that these products overall are producing fewer negative outcomes than drugs in schedule I or II.⁹⁵ The findings and conclusions communicated throughout the Factor 1 analysis are among the scientific and medical determinations of HHS that are accorded “significant deference” throughout the rest of the rulemaking process and may not be re-evaluated by DEA *de novo*.⁹⁶

A summary of key findings and conclusions discussed in the Proposed Rule follows below. Where appropriate or where updated epidemiological data is available, we provide additional information to supplement HHS’s analysis. The data reviewed strongly supports HHS’s abuse potential determinations.

1. Criterion 1: Whether there is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community

a. Summary: 2024 Proposed Rule and HHS’s 2023 Analysis

HHS gathered and reviewed available data to determine whether there is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community. While HHS’s review found that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community, HHS found that the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others.⁹⁷

⁹⁴ NPRM, 89 Fed. Reg. at 44,603.

⁹⁵ HHS Basis for Rec. at 62.

⁹⁶ 48 Op. O.L.C. ___, *supra* note 8, at 23–26.

⁹⁷ NPRM, 89 Fed. Reg. at 44,601; HHS Basis for Rec. at 6–7, 28–57 (data supporting this conclusion discussed in HHS’s analysis of Factors 4, 5, and 6).

Data supporting this conclusion were discussed in the Factor 1 analysis, as well as in Factors 4, 5, and 6 of the 8FA, and are drawn from established epidemiological databases, including, but not limited to: the National Survey on Drug Use and Health (“NSDUH”), the Behavioral Risk Factor Surveillance System (“BRFSS”), the Research Abuse, Diversion and Addiction-Related Surveillance (“RADARS”) System’s Nonmedical Use of Prescription Drugs (“NMURx”) Program, Monitoring the Future (“MTF”), the Youth Risk Behavior Surveillance System (“YRBSS”), the International Cannabis Policy Study (“ICPS”), the National Poison Data System (“NPDS”), the Treatment Episode Data Set (“TEDS”), the National Addictions Vigilance Intervention and Prevention Program (“NAVIPPRO”), the Nationwide Emergency Department Sample (“NEDS”), the National Inpatient Sample (“NIS”), and the Drug Abuse Warning Network (“DAWN”). As noted above, reliance on these types of databases is consistent with FDA recommendations in guidance regarding the abuse-potential analysis.⁹⁸

HHS’s 2023 Analysis and the 2024 Proposed Rule show that the agency evaluated marijuana abuse on a standalone basis as well as relative to other controlled substances used nonmedically and abused. HHS also evaluated alcohol, an uncontrolled substance. Contextually, HHS observed that from 2015 to 2019, the prevalence of past-year use of alcohol was five to six times greater than marijuana use, while past-year nonmedical use of heroin, cocaine, oxycodone, hydrocodone, tramadol, benzodiazepines, and zolpidem was four to five times less than marijuana.⁹⁹ What HHS deemed “the most notable conclusion” from its epidemiological assessment of adverse outcomes of nonmedical use of marijuana or comparator drugs from 2015 to 2021 arose in the individual health harms discussion.¹⁰⁰ Namely, HHS found that the utilization-adjusted rate of adverse outcomes involving marijuana was **consistently lower** than for heroin (schedule I), cocaine (schedule II), and other comparators for certain outcomes. Evidence of harmful consequences associated with marijuana abuse did exist, HHS found, but they appeared to be relatively less common and less severe than comparator drugs.¹⁰¹

With respect to the public health risks posed by marijuana, HHS found that they were lower for marijuana than for other drugs of abuse such as heroin (schedule I), oxycodone (schedule II), and cocaine (schedule II). Supporting HHS’s findings were epidemiological database evaluations for emergency department (“ED”) visits, hospitalizations, unintentional exposures, and overdose deaths. The rank order of the comparators in terms of greatest adverse consequences typically ranked heroin, benzodiazepines, and cocaine first or in immediately subsequent positions, with marijuana in a lower place in the ranking, especially when HHS adjusted for

⁹⁸ FDA GUIDANCE, *supra* note 90, at 32.

⁹⁹ HHS Basis for Rec. at 7.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

utilization.¹⁰² Marijuana also was the **lowest** ranked substance among comparator drugs with respect to overdose death. HHS found that the evaluations showed consistency across databases, substances, and time, and thus concluded that although marijuana abuse produces clear evidence of a risk to public health, the risk is relatively lower than that posed by most other comparator drugs.¹⁰³

b. HHS's Criterion 1 Analysis Is Rational and Entitled to Deference.

As the above summary shows, HHS extensively reviewed epidemiological databases and analyzed data reflective of marijuana's abuse potential, both on its own and relative to a selection of comparators. The Criterion 1 analyses and comparisons are an exercise of the agency's scientific and medical decision-making and expertise, as is the selection of comparators supporting this analysis. The agency's approach was thorough and well supported by data; it was not remotely arbitrary and capricious. Further, HHS's scientific and medical determinations here receive deference and are not subject to de novo review.¹⁰⁴

Substances are neither used nor abused in a vacuum, and comparisons are inherent in scheduling determinations. Understanding substance abuse and contextualizing abuse facilitates a comprehensive understanding of the absolute and relative harms to individual and public health and safety. The selection of comparators facilitated a meaningful and contextual understanding of the individual and public health implications of use of marijuana and the comparators.

HHS was not obliged to pick a particular set of comparators. HHS chose comparators that represent a cross-section of controlled substances and drugs or substances that are used or abused (whether medically or nonmedically). These comparators have varying impacts on individual and public health—some having severe repercussions on both—and they are subject to varying levels of control and restriction. One of these comparators, alcohol, is not a controlled substance but is so heavily used and abused in the United States that to exclude alcohol from the comparison would detract from a comprehensive understanding of marijuana's relative abuse potential. Alcohol and marijuana are among the two psychoactive substances most often consumed by Americans.¹⁰⁵ Further, both marijuana and alcohol have an extensive history of use by the public and, as a result, their health effects have been rigorously studied and compared.

¹⁰² NPRM, 89 Fed. Reg. at 44,601.

¹⁰³ *Id.*

¹⁰⁴ 48 Op. O.L.C. ___, *supra* note 8, at 23–26.

¹⁰⁵ According to the 2022 National Survey on Drug Use and Health, 62.3% of those age 12 and older have consumed alcohol in the past year, 22% have consumed cannabis, and 17.8% have consumed cigarettes. SAMHSA, *2022 National Survey on Drug Use and Health*, <https://www.samhsa.gov/data/release/2022-national-survey-drug-use-and-health-nsduh-releases#detailed-tables>.

For example, it is well established that alcohol—when consumed to excess in a short period of time—can cause lethal overdose and that several thousand Americans die each year because of alcohol poisoning.¹⁰⁶ Alcohol is also a contributing factor to more than 1 in 6 opioid overdose deaths, according to the National Institute on Alcohol Abuse and Alcoholism.¹⁰⁷ By contrast, THC—the primary psychoactive ingredient in marijuana—**cannot** cause lethal overdose, regardless of the quantity ingested. Specifically, data published in *The American Scientist* reported that the “ratio of fatal dose to effective dose” is 10 to 1 for alcohol, but such a ratio could not be calculated for marijuana.¹⁰⁸ Further, DEA’s own literature acknowledges, “No deaths from overdose of marijuana have been reported.”¹⁰⁹

Overall, alcohol abuse in this country is estimated to contribute to more than 178,000 deaths annually, making it “one of the leading preventable causes of death in the United States.”¹¹⁰ No comparable estimates for marijuana are available, nor does any public health agency publicly opine that marijuana is a comparable contributor to mortality in the United States. In fact, several longitudinal studies have failed to link marijuana use to any increased risk of premature death¹¹¹—including deaths due to lung¹¹² and other tobacco-related cancers,¹¹³ after researchers adjusted for potential confounders.

Understanding and evaluating absolute and relative harms, from an epidemiological and public health perspective, does not demand that the comparator products be drawn from a particular class of products in a particular schedule (e.g., schedule I hallucinogens), nor does it require comparisons only among products with pharmacologically similar mechanisms of action. Pharmacologic mechanisms of action are irrelevant to comparing the outcomes of substance abuse, such as overdose, ED visits, and poison control data, for example.

¹⁰⁶ Esser et al., *supra* note 25.

¹⁰⁷ *Alcohol-Related Emergencies and Deaths in the United States*, *supra* note 24.

¹⁰⁸ Gable, *supra* note 30.

¹⁰⁹ *Drug Fact Sheet*, *supra* note 29.

¹¹⁰ *Alcohol-Related Emergencies and Deaths in the United States*, *supra* note 24. This total includes deaths attributable to alcohol-induced health conditions, like cirrhosis.

¹¹¹ See, e.g., S. Andréasson et al., *supra* note 31 (“After controlling for social background variables in a multivariate model, no excess mortality was found.”); S. Sidney et al., *supra* note 31 (“Marijuana use in a prepaid health care-based study cohort had little effect on non-AIDS mortality in men and on total mortality in women.”); Edison Manrique-Garcia et al., *supra* note 31 (“The authors found an excess mortality among subjects with psychotic disorders, but the level [of excess mortality] did not differ between those with a history of cannabis use and those without such a history.”).

¹¹² Donald P. Tashkin et al., *supra* note 32 (“On balance, the available evidence at least thus far does not suggest that marijuana smoking poses an increased risk of lung cancer when adjustments are made for concomitant tobacco smoking.”).

¹¹³ S. Sidney et al., *supra* note 33 (“Marijuana use also was not associated with tobacco-related cancers or with cancer of the following sites: colorectal, lung, melanoma, prostate, breast, cervix.”).

In sum, evaluation of controlled substance comparators and selection of appropriate comparators necessarily demands scientific and medical expertise and is a scientific and medical determination warranting deference, which may not be substituted by DEA or the Biden Administration more generally.¹¹⁴

Finally, HHS's approach to the Criterion 1 analysis is also consistent with the demands of a scheduling analysis. A scheduling analysis is inherently comparative. For example, determining whether a substance belongs in schedule III (and higher schedules, such as schedule IV) demands a comparison of the substance's abuse potential to schedule II comparators because schedule III controlled substances have a lower potential for abuse than drugs in schedules I and II. Refusal to evaluate schedule I, II, III, and IV comparators versus marijuana would preclude HHS from fully and properly evaluating the appropriate schedule for marijuana and communicating its scientific and medical determinations to DEA.

c. Additional Evidence

In the 2024 Proposed Rule, DEA remarked that additional information on cannabis-related ED visits and updated epidemiological survey data since 2022 may be appropriate for consideration. A review of key epidemiological databases relied upon by HHS identified many that were updated since HHS's 2023 Analysis (e.g., NSDUH, BRFSS, MTF, YRBSS, NPDS, TEDS, NEDS, NIS, National Forensic Laboratory Information System ("NFLIS"), and DAWN). Key updates to epidemiological databases are discussed herein. Additionally, we provide other data points to contextualize risk of marijuana abuse on public health and discuss other indicators of impact on public health associated with marijuana use.

i. Epidemiology Database Updates

As noted above, DEA stated that information from updated epidemiological databases relied upon by HHS may be appropriate for consideration. Below is a table of databases reviewed that conveys whether the data was updated versus what was cited in HHS's recommendation.

| Data Set | Years Cited in HHS Recommendation | Most Recent Publication |
|--|-----------------------------------|-------------------------|
| National Survey on Drug Use and Health | 2015-2019*, 2020, 2021 | 2022 |
| Behavioral Risk Factor Surveillance System | 2021 | 2022 |
| Researched Abuse, Diversion and Addiction- | 2023 | 2023 |

¹¹⁴ 48 Op. O.L.C. ___, *supra* note 8, at 23–26.

| Related Surveillance System | | |
|---|------------|------------|
| Monitoring the Future | 2022 | 2024 |
| Youth Risk Behavior Surveillance System | 2019 | 2021 |
| International Cannabis Policy Study | 2019-2021 | 2021 |
| National Poison Data System | 2015-2021 | 2022 |
| Treatment Episode Data Set | 2015-2020 | 2021 |
| National Addictions Vigilance Intervention and Prevention Program | 2020-2021 | None |
| Nationwide Emergency Department Sample | 2016-2020 | 2021 |
| National Inpatient Sample | 2016-2020 | 2021 |
| National Forensic Laboratory Information System | 2021 | 2022 |
| Drug Abuse Warning Network | 2020, 2021 | 2022, 2024 |

*NSDUH data from 2020 and 2021 were discussed in HHS recommendations but could not be combined with previous data due to pandemic-related differences in data collection.

(a) National Survey on Drug Use and Health (“NSDUH”)

HHS’s 2023 Analysis relied on NSDUH data from 2015 to 2019, 2020, and 2021.¹¹⁵ Subsequent to HHS’s 2023 Analysis, NSDUH collected and published its 2022 data.¹¹⁶ Trends from the 2021 data analyzed by HHS are mostly able to be

¹¹⁵ Note, per HHS, direct comparisons between 2015-2019 data are not comparable to 2020 and 2021 data due to the differences in collection methods created by the COVID-19 pandemic. HHS Basis for Rec. at 32. NSDUH is an annual, nationally representative, cross-sectional household survey of individuals ages 12 years and older that provides information on the use of drugs and alcohol in the United States.

¹¹⁶ SAMHSA, *2022 National Survey on Drug Use and Health*, *supra* note 105.

evaluated as compared to the 2022 data. From 2021 to 2022, the past-year use of marijuana for any reason (nonmedical and medical) among people ages 12 years and older increased from 19% to 22%. Similar to the HHS analysis, past-year use (nonmedical and medical) of comparator drugs that have FDA-approved therapeutic indications declined or remained relatively stable, including hydrocodone (which decreased from 12.2% to 11.5%), benzodiazepines (1.4% to 1.3%), oxycodone (13% to 12%), tramadol (9.7% to 9.4%), zolpidem (9.6% to 8.1%), and ketamine (stable at 1.7%).

Over the same reporting period of 2021 to 2022, the prevalence of past-year use of alcohol remained stable between 62.3% and 62.8% for individuals ages 12 years and older, far exceeding the prevalence for marijuana or other comparator drugs. This data continues to demonstrate that alcohol has the highest prevalence of past-year use, followed by nonmedical use of marijuana. The prevalence of the other comparators is far below that of these two substances.

With respect to substance use disorder (“SUD”), NSDUH data show that among individuals with past-year heroin use in 2022, the prevalence of meeting the criteria for a heroin SUD was 86% (i.e., endorsing at least 2 of the 11 criteria for SUD (according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; severity data for heroin not available)). In 2021, this prevalence was 81%. For marijuana, the 2022 NSDUH data showed that the prevalence of meeting the criteria for marijuana SUD was as follows: 17% of individuals with past-year use had a mild SUD, 8% had a moderate SUD, and 5% had a severe SUD. As reported in the 2023 Analysis, the 2021 NSDUH data showed a 30% prevalence of meeting the criteria for marijuana SUD among individuals who used marijuana for nonmedical reasons only (17% mild, 8% moderate, and 5% severe). For individuals who used marijuana for nonmedical purposes and did not use other drugs illicitly, there was a slightly lower prevalence (24%) of meeting the criteria for SUD (15% mild, 6% moderate, and 3% severe).

There was a 27% prevalence of meeting criteria for cocaine SUD among individuals who used cocaine in the past year, with 10.5% of those with past-year cocaine use having a mild SUD, 4% having a moderate SUD, and 13% having a severe SUD. For those individuals who used alcohol in the past year, the prevalence of alcohol SUD was 17%, with 10% of individuals with past-year alcohol use having a mild SUD, 3% having a moderate SUD, and 3% having a severe SUD.

The 2022 NSDUH data continue to show that the likelihood of meeting the criteria for a SUD was highest for heroin, followed by marijuana/cocaine and then alcohol; however, the absolute number of individuals who met criteria for the specific drug SUD had a different rank order. The substance associated with the highest estimated number of individuals who met criteria for a specific SUD was alcohol (29,542,000), followed by marijuana (18,976,000), cocaine (1,435,000), and heroin (900,000).

(b) Monitoring the Future (“MTF”)

In the 2023 Analysis, HHS analyzed the 2022 MTF data.¹¹⁷ Subsequent to HHS’s analysis, MTF issued its 2024 report.¹¹⁸ In the 2024 MTF report, the organization noted that the COVID-19 pandemic may have contributed to some of the largest year-to-year decreases of continued substance use recorded in the project to date.¹¹⁹ This is particularly true for past 12-month use of marijuana, which from 2020 to 2021 had the largest ever declines recorded by the survey (since 1975 for 12th-grade students and since 1991 for 10th- and 8th-grade students).¹²⁰ The report continued, stating that 2023 results show that adolescent drug use levels for the most common substances continued at the lowered levels observed after the pandemic onset.¹²¹ Specifically, since the large drop in 2021, marijuana levels for past 12-month use changed little with no clear direction in any of the three grades (29% in 12th grade, 18% in 10th grade, and 8% in 8th grade).¹²² The 2024 MTF report also highlighted that levels of annual marijuana use today are considerably lower than the historic highs observed in the late 1970s, when more than half of 12th graders had used marijuana in the past 12 months.¹²³ Additionally, the prevalence of daily marijuana use for a month or more during one’s lifetime among 12th graders continued to hold steady at 12% in 2023. However, that figure was at 21% when first measured in 1982. The prevalence declined sharply to just 8% by 1992, rose back to 19% by 1997, and gradually declined to 12% by 2018, where it remains today.¹²⁴

Alcohol use generally followed a similar trend, with levels of past 12-month use for 12th-grade students slightly lower in 2023, at 46%, than they had been in 2021.¹²⁵ In 2023, 8th-grade levels of use were also slightly lower, at 15%, than in 2021.¹²⁶ Past 12-month alcohol use among 10th graders was the exception, with the 2023 level of 31% slightly higher than 2021 although substantially below the pre-pandemic level by 10 percentage points.¹²⁷ Also, in 2023, other comparator drugs (e.g., hydrocodone,

¹¹⁷ The COVID-19 pandemic may have potentially created a trend break relative to the 2020 MTF data. HHS Basis for Rec. at 35.

¹¹⁸ RICHARD A. MIECH ET AL., MONITORING THE FUTURE, NATIONAL SURVEY RESULTS ON DRUG USE, 1975-2023: OVERVIEW AND DETAILED RESULTS FOR SECONDARY SCHOOL STUDENTS (May 2024), <https://monitoringthefuture.org/wp-content/uploads/2024/01/mtfoverview2024.pdf> (“2024 MTF Report”).

¹¹⁹ 2024 MTF Report at 31.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.* at 86. Per the report, the 1970s high point “marked the pinnacle of a rise in marijuana use from relatively negligible levels before the 1960s.” *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 96.

¹²⁶ *Id.*

¹²⁷ *Id.*

heroin, tramadol, cocaine, ketamine) were each used in the past year by fewer than 5% of 12th graders.¹²⁸

(c) Youth Risk Behavior Surveillance System (“YRBSS”)

In the 2023 Analysis, HHS reviewed YRBSS data covering the 2009 to 2019 timeframe.¹²⁹ Subsequent to HHS’s review, CDC issued the 2011-2021 YRBSS report.¹³⁰ Data for 2021 showed a decline in marijuana use from historical data: 16% of students in 9th to 12th grade reported using marijuana at least once in the past month, down from approximately 20% in prior years.¹³¹ Past-month alcohol use by high school students, at 23%, was greater than marijuana use, though it also declined from prior surveys.¹³² Past-month prescription opioid misuse (including codeine, hydrocodone, or oxycodone), at 6%, was much lower than that of both alcohol and marijuana use, and also represents a decline relative to historical data.¹³³

(d) Treatment Episode Data Set (“TEDS”)

HHS reviewed the 2020 TEDS data for the 2023 Analysis. Subsequent to HHS’s review, SAMHSA issued the 2021 TEDS report.¹³⁴ This report presents findings from 1,482,543 admissions to substance use treatment services and 1,351,748 discharges from such services as reported by single state agencies in 2021.¹³⁵ Of note, among the 1.4 million admissions to substance use treatment services in 2021 by top 10 primary substances, 34.8% (n = 439,755) were for alcohol use, 20.2% (n = 255,401) were for heroin use, 13.5% (n = 170,220) were for

¹²⁸ *Id.* at 89–92.

¹²⁹ HHS Basis for Rec. at 36.

¹³⁰ CDC, Youth Risk Behavior Survey, Data Summary & Trends Report (2011-2021), https://www.cdc.gov/healthyyouth/data/yrbs/pdf/YRBS_Data-Summary-Trends_Report2023_508.pdf (“YRBSS Report”). YRBSS was established by the CDC and conducts school-based surveys every two years, in partnership with state, local, territorial, and tribal governments, with a focus on youth health behavior in the United States. The YRBSS high school component, the Youth Risk Behavior Survey, includes a nationally representative survey of 9th through 12th grade students.

¹³¹ YRBSS Report at 28.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ SAMHSA, Treatment Episode Data Set (TEDS) 2021: Admissions to and Discharges from Substance Use Treatment Services Reported by Single State Agencies (2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42794/2021-teds-annual-report.pdf> (“TEDS 2021 Report”). Note, “TEDS is a database run by SAMHSA within HHS that presents information on the demographic and substance use characteristics of annual admissions for treatment for alcohol and drug abuse in State-approved facilities that are required by the States to provide TEDS client-level data. Because TEDS is based only on reports from these facilities, TEDS data do not represent the total national demand for substance abuse treatment or the prevalence of substance abuse in the general population.” HHS Basis for Rec. at 40–41. Note also, TEDS represents admissions and discharges, not clients, because a client can have multiple treatment episodes each year. TEDS 2021 Report at 1.

¹³⁵ TEDS 2021 Report at 1.

methamphetamine use, 10.2% (n = 129,343) were for marijuana/hashish use, 9.1% (n = 115,273) were for other opiates/synthetics use, 5.6% (n = 70,456) were for cocaine use, 1.1% (n = 14,008) were for benzodiazepines use, 0.8% (n = 10,678) were for other amphetamines use, 0.3% (n = 3,911) were for phencyclidine (“PCP”) use, and 0.2% (n = 2,606) were for other stimulants use.¹³⁶ These rates are similar to rates in 2020. For example, as HHS noted in the 2023 Analysis, out of 1.4 million admissions documented in the 2020 TEDS data, the most frequently reported primary drug of admission was alcohol (31%, or 442,014 admissions), followed by heroin (21%, or 292,126 admissions), marijuana (10%, or 139,481 admissions), and cocaine (5%, or 71,725 admissions).¹³⁷

(e) National Forensic Laboratory Information System (“NFLIS”)

In the 2023 Analysis, HHS reviewed 2021 NFLIS data, and the updated 2022 data shows a decrease in the number of drug reports and marijuana/THC encounters.¹³⁸ In 2022, a total of 1,181,750 drug reports were identified by state and local forensic laboratories in the United States.¹³⁹ This estimate is a decrease of about 11% from the 1,326,205 drug reports identified during 2021.¹⁴⁰ Nationally, approximately three-fifths of all drugs reported in NFLIS-Drug were identified as methamphetamine (341,049 reports, or 29%), down from 45% in 2021; cocaine (169,972 reports, or 14%), down from 18% in 2021; marijuana/THC (146,631 reports, or 12%), down from 17% in 2021; or heroin (41,227 reports, or 3%), down from 8% in 2021.¹⁴¹ It is also noteworthy that the trend of marijuana/THC encounters continued its overall downward trajectory, which started in 2015.

¹³⁶ *Id.* at 10.

¹³⁷ HHS Basis for Rec. at 41.

¹³⁸ DEA, NATIONAL FORENSIC LABORATORY INFORMATION SYSTEM: NFLIS-DRUG 2022 ANNUAL REPORT, <https://www.nflis.deadiversion.usdoj.gov/nflisdata/docs/2022NFLIS-DrugAnnualReport.pdf> (“2022 NFLIS Report”). “The National Forensic Laboratory Information System (NFLIS) is a program of the Diversion Control Division of DEA. Data from the NFLIS-Drug system serves as a surveillance resource to monitor drug encounters by law enforcement across the United States (Drug Enforcement Administration). Specifically, the NFLIS-Drug system collects data on drugs seized by law enforcement during a law enforcement investigation, and which are submitted to federal, state, and local forensic laboratories for analysis.” HHS Basis for Rec. at 43.

¹³⁹ 2022 NFLIS Report at 4.

¹⁴⁰ HHS Basis for Rec. at 44.

¹⁴¹ 2022 NFLIS Report at 8.

(f) Drug Abuse Warning Network (“DAWN”)

In the 2023 Analysis, HHS reviewed the DAWN 2021 report, Findings from Drug-Related Emergency Department Visits. Subsequent to HHS’s review, SAMHSA published the 2022 and 2024 DAWN reports.¹⁴²

In 2022, DAWN identified 153,596 (unweighted) drug-related ED visits from 53 participating hospitals, and for weighted national estimates for all drug-related ED visits in 2022, the report stated that there were an estimated total of 7,714,521 drug-related ED visits in the United States in 2022.¹⁴³ Alcohol represented the highest percentage of drug-related ED visits (at 45.0%), followed by opioids (12.7%) and marijuana (11.9%).¹⁴⁴ This is similar to 2021 data, wherein the top five drugs involved in drug-related ED visits were alcohol (41.7%), opioids (14.79%), methamphetamine (11.29%), marijuana (11.19%), and cocaine (4.77%).¹⁴⁵

The 2022 DAWN report conveyed substance-related ED visits by age group, sex, and other demographic characteristics. In 2022, the largest rate of ED visits by age group was reported for individuals aged 26-44 years among the comparators evaluated, where alcohol (1,526 per 100,000) had the highest numbers, followed by marijuana (597 per 100,000), opioids (495 per 100,000), and cocaine (223 per 100,000).¹⁴⁶

The 2024 DAWN report focused on estimates of alcohol-related ED visits from January 2021 through September 2023. The report shows that 80% of ED visits were related to alcohol alone. The remaining approximately 20% involved alcohol plus additional substances.¹⁴⁷ Of these additional substances, only one-third were marijuana, for an overall involvement rate of marijuana in all ED visits related to any substance of approximately 7%. There is no comment on the rate of marijuana-only ED visits, and the data does not reflect whether the marijuana involved was synthetic IHDC products or actual marijuana.

¹⁴² DRUG ABUSE WARNING NETWORK (DAWN), FINDINGS FROM DRUG-RELATED EMERGENCY DEPARTMENT VISITS, 2022, <https://store.samhsa.gov/sites/default/files/pep23-07-03-001.pdf> (“2022 DAWN Report”); DRUG ABUSE WARNING NETWORK (DAWN), SHORT REPORT – ALCOHOL-RELATED ED VISITS (2024), <https://www.samhsa.gov/data/sites/default/files/reports/rpt44498/DAWN-TargetReport-Alcohol-508.pdf> (“2024 DAWN Report”). DAWN is a nationwide public health surveillance system that captures data on ED visits related to recent substance use directly from the electronic health records of participating hospitals.

¹⁴³ 2022 DAWN Report at 6.

¹⁴⁴ *Id.*

¹⁴⁵ DRUG ABUSE WARNING NETWORK (DAWN), FINDINGS FROM DRUG-RELATED EMERGENCY DEPARTMENT VISITS, 2021 at 1, <https://store.samhsa.gov/sites/default/files/pep22-07-03-002.pdf>.

¹⁴⁶ 2022 DAWN Report at 18, 23, 27, 35.

¹⁴⁷ 2024 DAWN Report at 2.

ii. Contextual Data and Public Health Risk

(a) Risks Associated with Over-the-Counter and Commonly Used Medications

Against the backdrop of the risk information obtained from epidemiological databases of marijuana and comparators, it is important to remember that medications, even those authorized for over-the-counter use to treat common conditions such as pain relief, also present risks. For example, non-steroidal anti-inflammatory drugs (“NSAIDs”) can cause gastrointestinal (“GI”) ulcers and bleeding, which can range from serious to fatal. Use of NSAIDs increases risk of GI bleeding 400% in general, and if used in concert with other medications such as corticosteroids, spironolactone, or selective serotonin reuptake inhibitors, can increase the risk of GI bleeding from 700% to 1,200%, depending on the medication used.¹⁴⁸ The risk of fatal GI bleed is 21% in the setting of NSAID use, whereas in patients not taking NSAIDs it is 7%.¹⁴⁹ NSAIDs are also associated with increased risk of heart attack, causing 7-9 non-fatal and 2 fatal heart attacks per 1000 persons per year over the general rate of heart attacks.¹⁵⁰ This could result in approximately four million excess heart attacks per year in the United States. Finally, in persons over age 65, NSAIDs are associated with double the risk of kidney failure for 30 days after use.¹⁵¹

Aspirin, similarly, can lead to a small but real (14%) increase in all-cause mortality.¹⁵² In a study of 19,114 individuals in the United States ages 70 and older (or 65 and up among Blacks and Hispanics in the United States), who did not have cardiovascular disease, dementia, or disability, and were randomly assigned to receive 100 mg of enteric-coated aspirin or placebo, higher all-cause mortality was observed among apparently healthy older adults who received daily aspirin than among those who received placebo. This differential was primarily attributed to cancer-related death. As the authors noted, in the context of previous studies, this result was unexpected and should be interpreted with caution.

Acetaminophen, the generic name for the brand-name product Tylenol®, can be toxic to the liver. It is estimated to be responsible for approximately 350 deaths per year and was implicated in the onset of more than 50% of patients with acute

¹⁴⁸ See Abigail Davis & John Robson, *The dangers of NSAIDs: look both ways*, 66 BRIT. J. GEN. PRAC. 172-73 (Apr. 2016), <https://bigp.org/content/66/645/172#:~:text=From%20the%20first%20day%20of%20use%2C%20all%20NSAIDs,of%20inhibition%20of%20the%20enzymes%20COX-1%20and%20COX-2.>

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² John J. McNeil et al., *Effect of Aspirin on All-Cause Mortality in the Healthy Elderly*, 379 New Eng. J. of Med. 1519-28 (Sept. 16, 2018), <https://www.nejm.org/doi/full/10.1056/NEJMoa1803955>.

liver failure.¹⁵³ Proton-pump inhibitors appear to be responsible for excess all-cause mortality between 3% and 20%.¹⁵⁴

By comparison to marijuana, all of these medications pose greater risk to health. Risk of medical consequences associated with marijuana can include cannabis use disorder, increased anxiety, potential for psychoticism, and potential effects on perinatal outcomes. However, none of these risks occur with sufficient frequency to even remotely approach the actual risk associated with the substances discussed above.¹⁵⁵

(b) Alcohol-Related Risks, Including Compared to Marijuana

Alcohol poses a different calculus. Alcohol leads to 178,000 excess American deaths per year and accounts for over 17% of all ED visits.¹⁵⁶ An even greater number of ED visits are complicated by the acute or chronic effects of alcohol. Alcohol consumption is also associated with an elevated risk of “anger, hostility, and aggressive behaviors.”¹⁵⁷ Experts suggest that alcohol consumption “can reduce self-control and the ability to process incoming information and assess risks, and can increase emotional lability and impulsivity, [thereby making] certain drinkers more likely to resort to violence in confrontation.”¹⁵⁸ Furthermore, findings from brain studies indicate that “long-term alcohol consumption induce[s] morphological changes in brain regions involved in self-control, decision-making, and emotional processing.”¹⁵⁹ Of course, alcohol is not on the list of controlled substances at all, while marijuana is currently a schedule I drug.

¹⁵³ William M. Lee, *Acetaminophen and the U.S. acute liver failure study group: Lowering the risks of hepatic failure*, 40 HEPATOLOGY 6–9 (July 2004) <https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.20293>.

¹⁵⁴ Mohamed Ben-Eltriki et al., *Do Proton Pump Inhibitors Increase Mortality? A Systematic Review and In-Depth Analysis of the Evidence*, PHARMACOLOGY RSCH. & PERSPS. (Oct. 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7525804/>.

¹⁵⁵ Heng Shao et al., *Trends of the Global Burden of Disease Attributable to Cannabis Use Disorder in 204 Countries and Territories, 1990–2019: Results from the Disease Burden Study 2019*, INT’L J. MENTAL HEALTH & ADDICTION (2023), <https://www.issup.net/files/2023-05/Trends%20of%20the%20Global%20Burden%20of%20Disease%20Attributable%20to%20Cannabis%20Use%20Disorder%20in%20204%20Countries%20and%20Territories%2C%201990%E2%80%932019%20-%20Results%20from%20the%20Disease%20Burden%20Study%202019.pdf>.

¹⁵⁶ Aaron M. White et al., *Trends in Alcohol-Related Emergency Department Visits in the United States: Results from the Nationwide Emergency Department Sample, 2006 to 2014*, 42 ALCOHOLISM: CLINICAL & EXPERIMENTAL RSCH. (Feb. 2018).

¹⁵⁷ Mado Gautier et al., *Anger, Hostility, and Aggression in Severe Alcohol Use Disorder*, HANDBOOK OF ANGER, AGGRESSION, AND VIOLENCE (2023), https://link.springer.com/referenceworkentry/10.1007/978-3-031-31547-3_48.

¹⁵⁸ WORLD HEALTH ORG., YOUTH ALCOHOL AND VIOLENCE (2006), <https://www.who.int/docs/default-source/documents/child-maltreatment/youth-violence-and-alcohol.pdf>.

¹⁵⁹ Kajol V. Sontate et al., *Alcohol, Aggression, and Violence: From Public Health to Neuroscience*, 12 FRONTIERS IN PSYCH. (Dec. 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8729263/>.

By contrast, marijuana exposure has not been established to produce changes in brain morphology like those associated with alcohol abuse.¹⁶⁰ Nor does marijuana share the same association with violent behavior as does alcohol. According to a meta-analysis of the relevant literature, with the exception of cases where individuals “have a unique susceptibility for engaging in violent behavior,” any relationship between marijuana and violence is “strictly correlational.”¹⁶¹

Alcohol’s risks to the public health extend beyond those that negatively impact the individual user. Over their lifetime, more than one third of U.S. adults “are harmed by someone else’s drinking,” according to data compiled by the Alcohol Research Group.¹⁶² Harms include traffic accidents, vandalism, physical harm, financial issues, legal issues, and family or marriage problems, among others. Specifically, data published in 2024 in the *Journal of Studies on Alcohol and Drugs* determined that 34.2% of adults have experienced “secondhand harms from alcohol.”¹⁶³ By contrast, the same study found that only 5.5% of adults had ever experienced secondhand harms due to others’ marijuana use.¹⁶⁴ Of those citing secondhand harms from marijuana, many acknowledged hardships arising from its prohibitive status—such as experiencing financial harms because of a failed drug test—rather than from someone else’s misuse of the substance.

With respect to traffic accidents and public health risk, the data reviewed shows that marijuana is also a far less significant contributor than alcohol to motor vehicle accidents. Specifically, a prospective case-control study by the National Highway Traffic Safety Administration determined that THC-positive drivers possess virtually no greater risk of being involved in a motor vehicle crash (Odds Ratio 1.05) than drug-free drivers after researchers controlled for confounders (age and gender). By contrast, drivers in the same study with a blood alcohol level of 0.08 possessed a nearly four-fold crash risk (Odds Ratio 3.93) compared to drug-free

¹⁶⁰ Barbara J. Weiland et al., *Daily marijuana Use is Not Associated with Brain Morphometric Measures in Adolescents or Adults*, 35 J. OF NEUROSCIENCE, 1505-12 (Jan. 28, 2015), <https://www.jneurosci.org/content/35/4/1505.short> (“In sum, the results indicate that, when carefully controlling for alcohol use, gender, age, and other variables, there is no association between marijuana use and standard volumetric or shape measurements of subcortical structures. ... [I]t seems unlikely that marijuana use has the same level of long-term deleterious effects on brain morphology as other drugs like alcohol.” *Id.* at 1505, 1510).

¹⁶¹ Dorsa Rafiei & Nathan J. Kolia, *Fact or Fiction Regarding the Relationship Between Cannabis Use and Violent Behavior*, 50 J. OF AM. ACAD. OF PSYCHIATRY & THE LAW (Dec. 10, 2021), <https://jaapl.org/content/early/2021/12/10/JAAPL.210034-21.long>.

¹⁶² Press Release, Alcohol Research Group, Alcohol and Drug Use Cause Significant Harms that Go Beyond the Individual (June 3, 2024), <https://arg.org/news/alcohol-and-drug-use-cause-significant-harms-that-go-beyond-the-individual/>.

¹⁶³ E.M. Rosen et al., *Prevalence and Correlates of Alcohol and Drug Harms to Others: Findings from the 2020 US National Alcohol Survey*, 23 J. OF THE STUD. ON ALCOHOL & DRUGS (June 2024), <https://www.jsad.com/doi/10.15288/jsad.23-00387U>.

¹⁶⁴ *Id.*

drivers, even after researchers controlled for the same confounders.¹⁶⁵ This conclusion is consistent with those of other studies finding that drivers who test positive for the presence of THC alone possess low¹⁶⁶ to no¹⁶⁷ elevated motor vehicle crash risk, whereas alcohol-positive drivers possess a nearly six-fold risk of accident.¹⁶⁸ This stark contrast is likely because those subjects under the influence of THC typically engage in compensatory driving behaviors,¹⁶⁹—including reducing their mean speed¹⁷⁰ and leaving greater headway between themselves and the cars in front of them¹⁷¹—whereas drivers under the influence of alcohol often drive in a more reckless manner and engage in more risk-taking behaviors. ED data similarly reflects¹⁷² that those who test positive for alcohol are far more likely to be in a motor vehicle accident requiring emergency care than are those who test positive for marijuana.¹⁷³

Like HHS, other experts around the world have also compared the public health effects of marijuana and other controlled substances, including alcohol. Specifically, a study published in *The Lancet* assessed the harmful effects of various

¹⁶⁵ Richard P. Compton & Amy Berning, *Drug and Alcohol Crash Risk*, U.S. DEP'T OF TRANSP. TRAFFIC SAFETY FACTS RESEARCH NOTE (Feb. 2, 2015), <https://rosap.nhtl.bts.gov/view/dot/1993>.

¹⁶⁶ Ole Rogeberg, A meta-analysis of the crash risk of cannabis-positive drivers in culpability studies—Avoiding interpretational bias, 123 ACCIDENT ANALYSIS & PREVENTION 69-78 (Feb. 2019), <https://pubmed.ncbi.nlm.nih.gov/30468948/> (“Culpability ORs exaggerate risk increases and parameter uncertainty when misinterpreted as total crash ORs. The increased crash risk associated with THC-positive drivers in culpability studies is low.”).

¹⁶⁷ Jeffrey R. Brubacher et al., *Cannabis use as a risk factor for causing motor vehicle crashes: a prospective study*, 114 ADDICTION 1616-26 (July 3, 2019), <https://pubmed.ncbi.nlm.nih.gov/31106494/> (“In this multi-site observational study of non-fatally injured drivers we found no increase in crash risk, after adjustment for age, sex and use of other impairing substances, in drivers with THC < 5 ng/ml. For drivers with THC ≥ 5 ng/ml there may be an increased risk of crash responsibility (OR = 1.74), but this result was statistically non-significant and further study is required.”).

¹⁶⁸ *Id.* See also Guohua Li et al., *Role of alcohol and marijuana use in the initiation of fatal two vehicle crashes*, 26 ANNALS OF EPIDEMIOLOGY 342–47 (May 2017), <https://www.sciencedirect.com/science/article/abs/pii/S1047279716304380> (“[T]he adjusted odds ratios of fatal crash initiation were 5.37 . . . for those testing positive for alcohol and negative for marijuana, 1.62 . . . for those testing positive for marijuana and negative for alcohol[.]”).

¹⁶⁹ Aki Ronen et al., *Effects of THC on driving performance, physiological state and subjective feelings relative to alcohol*, 40 ACCIDENT ANALYSIS & PREVENTION 926–34 (May 2008), <https://pubmed.ncbi.nlm.nih.gov/18460360/>.

¹⁷⁰ S. Zhao et al., *The effect of cannabis edibles on driving and blood THC*, 6 J. OF CANNABIS RSCH. (May 31, 2024), <https://pubmed.ncbi.nlm.nih.gov/38822413/>.

¹⁷¹ R. Andrew Sewell et al., *The effect of cannabis compared with alcohol on driving*, 18 AM. J. ON ADDICTIONS 185–93 (May-June 2009), <https://pubmed.ncbi.nlm.nih.gov/19340636/>.

¹⁷² J.R. Brubacher et al., *High-‘n’-dry? A comparison of cannabis and alcohol use in drivers presenting to hospital after a vehicular collision*, 118 ADDICTION 1507–16 (Mar. 30, 2023), <https://pubmed.ncbi.nlm.nih.gov/36898848/>.

¹⁷³ Esther K. Choo et al., *Risk of motor vehicle collision associated with cannabis and alcohol use among patients presenting for emergency care*, 198 ACCIDENT; ANALYSIS & PREVENTION (Jan. 25, 2024), <https://pubmed.ncbi.nlm.nih.gov/38277855/> (“Cannabis alone was not associated with higher odds of MVC [motor vehicle accident], while acute alcohol use alone . . . [was] independently associated with higher odds of MVC.”).

controlled substances upon both the public and the individual user. The study's authors concluded, "Overall, alcohol was the most harmful drug, with heroin and crack cocaine in second and third places."¹⁷⁴ A separate review, published in the journal *Current Opinion in Pharmacology*, similarly determined that cannabis use—even long-term—possesses a superior safety profile compared to most other substances. It concluded, "Overall, by comparison with other drugs used mainly for 'recreational' purposes, cannabis could be rated to be a relatively safe drug."¹⁷⁵ Another review assessing the relative physical, psychological, and social harms of marijuana and alcohol similarly concluded, "A direct comparison of alcohol and cannabis showed that alcohol was considered to be more than twice as harmful as cannabis to [individual] users, and five times more harmful as cannabis to others."¹⁷⁶

Notably, it is not solely the act of alcohol consumption that can adversely impact users' health. In fact, ceasing one's use of alcohol can pose serious health risks in certain circumstances. For longtime habitual abusers of alcohol, withdrawing from the drug may trigger delirium tremens—a condition characterized by body tremors, hallucinations, and even cardiovascular collapse.¹⁷⁷ By comparison, marijuana-associated withdrawal is typically characterized by feelings of anxiety, irritability, and disturbed sleep, among other symptoms.¹⁷⁸ These symptoms are generally short lived and, for most people, not clinically significant.¹⁷⁹

In conclusion, HHS's determination that marijuana use does not pose the same public health burden as alcohol consumption is consistent with decades of worldwide scientific literature.

(c) Analytical Comparison of Fentanyl to Marijuana

In considering the HHS analysis of the actual or relative abuse potential of marijuana and the agency's decision to recommend a schedule III classification for marijuana, it is instructive to compare that analysis with the first factor analysis of fentanyl, classified as schedule II, to demonstrate that HHS's recommendation is reasonable and most likely conservative in nature.

A comparative analysis of the evidence for fentanyl and marijuana related to taking the substance in amounts sufficient to create hazard to the health or to the

¹⁷⁴ David J. Nutt et al., *Drug harms in the UK: a multicriteria decision analysis*, 376 THE LANCET 1524–25 (Nov. 6, 2010), <https://pubmed.ncbi.nlm.nih.gov/21036393/>.

¹⁷⁵ Leslie Iverson, *Long-term effects of exposure to cannabis*, 5 CURRENT OP. IN PHARMACOLOGY 69–72 (Feb. 2005), <https://pubmed.ncbi.nlm.nih.gov/15661628/>.

¹⁷⁶ Ruth Weissenborn R & David J. Nutt, *Popular intoxicants: what lessons can be learned from the last 40 years of alcohol and cannabis regulation?*, 26 J. of Psychopharmacology 213–20 (Feb. 2012), <https://pubmed.ncbi.nlm.nih.gov/21926420/>.

¹⁷⁷ Toohey, *supra* note 34.

¹⁷⁸ Connor, *supra* note 35.

¹⁷⁹ Preuss, *supra* note 36.

safety of other individuals or to the community yields stark differences. In 2022, approximately 61,901,000 individuals reported past-year marijuana use versus 3,086,000 individuals reporting past-year use of fentanyl. While there are significantly more marijuana users, fentanyl, unlike marijuana, taken in sufficient amounts creates the health hazard of overdose in individuals. In 2022, there were approximately 65,000 nonfatal, non-heroin opioid overdoses,¹⁸⁰ most likely attributable to fentanyl. The number of fatal overdoses attributable to fentanyl in 2022 is estimated to be 76,226 individuals.¹⁸¹ The toll of these lost lives on the community is significant—in 2017, the economic cost of opioid use disorder and fatal opioid overdose was \$150 billion. In addition, noneconomic costs of \$871 billion are estimated to be attributable to reduced quality of life from opioid use disorder and the value of life lost due to fatal opioid overdoses.¹⁸² Cannabis, by comparison, had 14,506 single substance exposures captured in poison center data, resulting in 10,240 health care facility admissions and zero deaths.¹⁸³ As we explain in detail below, this data is skewed because “cannabis” also encompasses unregulated, untested, synthetically-produced intoxicating hemp products.

2. Criterion 2: Whether there is significant diversion of the drug or drugs containing such a substance from legitimate drug channels

In 2023, HHS found a lack of evidence of significant diversion from legitimate drug channels (i.e., marijuana legally marketed under U.S. federal law), attributable to the fact that a new drug application for a drug product containing botanical marijuana has not been approved for marketing in the United States.¹⁸⁴ Currently, limited legitimate, federally sanctioned drug channels in the United States are limited to research and related manufacturing authorizations (clinical research under investigational new drug applications and DEA-registrants that are approved to produce marijuana and derived formulations for use in DEA-authorized nonclinical and clinical research). HHS found a lack of data indicating diversion occurring from these entities or activities. HHS also recognized, however, significant additional sources of marijuana in the United States, including illicit cultivation, production,

¹⁸⁰ CDC, *Drug Overdose Surveillance and Epidemiology (DOSE) System: Nonfatal Overdose Emergency Department and Inpatient Hospitalization Discharge Data* (updated Jan. 22, 2024), <https://www.cdc.gov/overdose-prevention/data-research/facts-stats/dose-dashboard-nonfatal-discharge-data.html>.

¹⁸¹ CDC Press Release, *supra* note 27.

¹⁸² Curtis Florence et al., *The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017*, 218 *DRUG & ALCOHOL DEPENDENCE* (Jan. 1, 2021), <https://www.sciencedirect.com/science/article/abs/pii/S0376871620305159?via%3Dihub>.

¹⁸³ David D. Gummin et al., *2022 Annual Report of the National Poison Data System® (NPDS) from America's Poison Centers®: 40th Annual Report*, 61 *CLINICAL TOXICOLOGY* 717–939 (2023), <https://piper.filecamp.com/uniq/P2nQIZD7062jaPpg.pdf>.

¹⁸⁴ NPRM, 89 Fed. Reg. at 44,602.

importation, and from state programs that permit dispensing of marijuana for medical and recreational use.

We note DEA's observation that in light of this "unique landscape," the lack of data indicating diversion of marijuana from federally sanctioned drug channels is not indicative of a lack of abuse potential of the drug. But the fact that diversion is not occurring or a lack of evidence of significant diversion exists is certainly not evidence that marijuana has abuse potential or a high potential for abuse. And it answers the question posed by Criterion 2—whether significant diversion is occurring.

We further note that comparing marijuana to a substance with a high potential for abuse, fentanyl, with respect to diversion from legitimate drug channels, reveals significant differences. According to the DEA NFLIS, data for fentanyl diversion remained steady from 2008 to 2013, but increased significantly from 2014 through 2022,¹⁸⁵ contemporaneous with a significant increase in the quantity of illicitly manufactured fentanyl. These data weaken the contention that availability of illicit sources of a substance should render lack of diversion from legitimate sources an unreliable indicator of a lack of abuse potential.

Finally, we are unaware of new data or evidence that affects or modifies HHS's and DOJ's conclusion communicated in the 2024 Proposed Rule regarding a lack of evidence of significant diversion.

3. Criterion 3: Whether individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of their professional practice

In the 2023 Analysis, HHS determined that outside of federal and state-sanctioned medical use, individuals are using marijuana on their own initiative for medical and nonmedical purposes. The federal route for sanctioned medical use is through clinical research under an FDA Investigational New Drug ("IND") application. At the state level, sanctioned medical use occurs under state law—authorized medical marijuana programs. Though DEA notes that data on the number of individuals using marijuana under state law is not available, we note that HHS referenced NSDUH data going back to 2015 regarding exclusive medical use of marijuana that was recommended by a health care practitioner: exclusive medical use of marijuana that was recommended by an HCP ranged from 7% to 8% between 2015 and 2019, increased to 10% in 2020, and decreased to 9% in 2021.¹⁸⁶ DEA also referenced 2022 NSDUH marijuana usage prevalence data among people aged 12 and older in the United States: 61.9 million people (22%) reported using marijuana in the past year (a 16% increase over 2021 data considered by HHS), 42.3 million people

¹⁸⁵ See NFLIS-DRUG 2022 Annual Report, *supra* note 138, at 11.

¹⁸⁶ HHS Basis for Rec. at 33.

used marijuana in the past month, and marijuana was the illicit drug used with greatest frequency. In 2021, marijuana was also the illicit drug used with greatest frequency, with 18.7% of people aged 12 or older (52.5 million people) using it in the past year. Increases in usage are anticipated in light of the number of states that legalized recreational use of marijuana in 2021 (four) and 2022 (three) and medical use of marijuana in 2021 (one) and 2022 (one), although the launch of state medical and recreational programs can encounter delays.¹⁸⁷

DEA also remarked that updated epidemiological survey data since 2022 may be appropriate for consideration. Updates to key epidemiological databases are provided in the Criterion 1 discussion, and as noted above, are generally consistent with, not materially different from, HHS's 2023 Analysis, or show declines in use and adverse outcomes (e.g., TEDS and MTF). In short, updated epidemiological databases continue to show that individuals are using marijuana on their own initiative for medical and nonmedical purposes.

4. **Criterion 4: Whether the drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that it will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that they have a substantial capability of creating hazards to the health of the user or to the safety of the community**

In the 2023 Analysis, HHS found that epidemiological data indicate that marijuana has the potential for creating hazards to the health of the user and safety of the community.¹⁸⁸ But, with respect to marijuana's relative abuse liability as compared to heroin, oxycodone, hydrocodone, fentanyl, cocaine, ketamine, benzodiazepines, zolpidem, tramadol, and alcohol in epidemiological databases, marijuana is not typically among the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder.¹⁸⁹ The agency also noted that marijuana has been controlled in schedule I of the CSA since its enactment in 1980. There are, as HHS stated, extensive nonclinical and clinical studies that establish that marijuana, due to the cannabinoid CB₁ receptor agonist activity of its main cannabinoid constituent delta-9 THC, produces rewarding effects that would be consistent with observed long-term patterns of nonmedical use and abuse, both before and in years since enactment of the CSA.¹⁹⁰ Additionally,

¹⁸⁷ *Where marijuana is legal in the United States*, MJBIZDAILY (Nov. 13, 2023), <https://mjbizdaily.com/map-of-us-marijuana-legalization-by-state/>.

¹⁸⁸ HHS Basis for Rec. at 9.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

abuse-related studies for two drug products containing dronabinol—Marinol (schedule III) and Syndros (schedule II)—confirmed the abuse potential of delta-9 THC (also known as dronabinol, when specifically referring to the (-)-trans-delta-9-THC stereoisomer).¹⁹¹ These findings suggest that marijuana will continue to be used nonmedically, diverted from legitimate channels, and trafficked in illicit channels as a potential source for continued nonmedical use in the United States.

In the 2024 Proposed Rule, DEA had no comments on HHS’s analysis, nor did DEA seek to obtain more information with respect to this criterion. We are unaware of new data or evidence that affects or modifies the conclusion of HHS and DOJ communicated in the 2024 Proposed Rule, and similar to other criteria, HHS’s conclusions here are scientific and medical determinations that receive deference throughout the rulemaking process.¹⁹²

5. Marijuana Has a Low Potential for Abuse

In making its scheduling recommendation after considering the eight factors determinative of control of a substance, HHS recommended that marijuana be rescheduled from schedule I to schedule III because it meets the three criteria for placing a substance in schedule III.

Although HHS’s scheduling recommendations are not binding, the agency’s scientific and medical determinations receive deference—meaning these determinations that are foundational to the scheduling recommendation may not be reviewed *de novo*.¹⁹³

Of note, HHS observed that there is a high prevalence of nonmedical use of marijuana, but an overall evaluation of epidemiological indicators suggests that marijuana does not produce serious outcomes compared to schedule I or II drugs or substances. We further note that HHS addressed the challenges of conducting a

¹⁹¹ *Id.* We note that the fact that Syndros is in schedule II is not indicative of the appropriate schedule for marijuana. Syndros is an oral dronabinol (THC) solution whose physicochemical properties allow extraction of dronabinol for abuse through oral or inhalation (smoking or vaping) routes. Dronabinol is not easily extractable from Marinol and the drug is in schedule III. Marijuana as defined in the 2024 Proposed Rule is distinguishable from both products; as the 2024 Proposed Rule at 44,603 notes, cultivated chemovars may vary in their composition and concentration of various chemical constituents, including with respect to whether they contain significant amounts of delta-9 THC or other cannabinoids, and marijuana products from different strains will have differing biological and pharmacological profiles. Delta-9 THC is one of the most abundant cannabinoids present in marijuana (in addition to CBD, which has negligible abuse potential), but marijuana is a far more complex substance than Marinol or Syndros, and the abuse potential and scheduling of both is not determinative of marijuana’s absolute or relative abuse potential or schedule. Moreover, Syndros and Marinol contain *synthetic* delta-9 THC, which is separately scheduled as a schedule I substance and is not the subject of this NPRM. DEA Interim Final Rule, Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639, 51,641 (Aug. 21, 2020); NPRM, 89 Fed. Reg. at 44,620 (“This proposal would not apply to synthetically derived THC, which is outside the CSA’s definition of marijuana.”).

¹⁹² 48 Op. O.L.C. ___, *supra* note 8, at 23–26.

¹⁹³ *Id.*

comprehensive assessment of the relative abuse potential of marijuana.¹⁹⁴ HHS dealt with these challenges by “evaluating the totality of the available data and have concluded that it supports placement of marijuana in schedule III,” and concluded that “[o]verall, these data demonstrate that, while marijuana is associated with a high prevalence of abuse, the profile of and propensity for serious outcomes related to that abuse lead to a conclusion that marijuana is most appropriately controlled in schedule III under the CSA.” We firmly agree.

II. Abuse-Potential Data Is Systemically Skewed in Ways That Exaggerate Marijuana’s Abuse Potential.

1. The Proliferation of Unregulated, Untested, Intoxicating Hemp Has Distorted the Data on Marijuana’s Abuse Potential.

HHS’s rescheduling analysis includes a scientific and medical evaluation and scheduling recommendation for marijuana within the meaning of marijuana in the CSA. HHS reviewed marijuana for its accepted medical use as well as its abuse potential and level of physical or psychological dependence. Data and analysis reveals the failure to meaningfully account for negative outcomes associated with comparable cannabinoids derived from industrial hemp. Troublingly, those excluded have been chemically modified or converted from hemp cannabidiol (“CBD”), specifically delta-8 THC and delta-9 THC, as well as delta-10 THC, tetrahydrocannabinol-O-acetate (“THC-O-acetate”), hexahydrocannabinol (“HHC”), THC-P, and other THC isomer analogs or derivatives (many of which would, in accordance with the rescheduling recommendation, remain controlled as schedule I). By failing to differentiate between marijuana-derived cannabinoids and synthetic intoxicating hemp-derived cannabinoids (“IHDCs”), the data collection obscures the true impacts and safety profiles of both hemp-derived and marijuana-derived products. We therefore contend that when the adverse event data is overlaid with the timing of the 2018 Farm Bill and the size and scope of the synthetic IHDC market, there are direct correlations and causations that are incorrectly attributed to marijuana.¹⁹⁵

DOJ’s NPRM excludes hemp-type cannabis from marijuana’s schedule I control status to reflect the provisions of the 2018 Agricultural Improvement Act (i.e., the “Farm Bill”¹⁹⁶), which defined hemp as *Cannabis sativa L.* and its derivatives with no more than 0.3 percent delta-9 THC on a dry weight basis, and explicitly

¹⁹⁴ These challenges can include confounding factors that may affect the adverse outcomes measured in epidemiological databases and influence the rank ordering of drugs evaluated on such measures, and it can be difficult to reconcile the ranking of relative harms associated with comparators when the rankings differ across various epidemiological databases and often do not align with how the products are scheduled in the CSA. HHS Basis for Rec. at 63.

¹⁹⁵ A. Hazekamp & J.T. Fischeidick, *Cannabis—From Cultivar to Chemovar*, 4 DRUG TESTING & ANALYSIS 660–67 (Feb. 24, 2012) (discussing the complexities of cannabinoid profiles and the importance of source-specific data in understanding their impacts).

¹⁹⁶ Agriculture Improvement Act of 2018 (“2018 Farm Bill”), P. L. No. 115-334, 132 Stat. 4490, <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

revised the definition of marijuana in the CSA to exclude, and effectively decontrol, hemp.¹⁹⁷ This statutory 0.3% delta-9 THC threshold metric was intended to differentiate industrial hemp as nonintoxicating from marijuana and limit the amount of delta-9 THC in any hemp product to a *de minimis* level. But, due to questionable statutory drafting, it has instead allowed for the rapid proliferation and sale of IHDCs around the country. These IHDCs include compounds that have undergone synthetic chemical conversions from hemp, are sold online and across the United States, and are particularly popular in states with no legal marijuana framework. These IHDC products typically have delta-9 THC potencies that are equal to or significantly higher than the intoxicating products sold in state-regulated marijuana markets. Perhaps of greatest concern is the widespread, nationwide sale of IHDC products that include synthetic cannabinoids which are explicitly prohibited in many state-legal marijuana markets due to health and safety concerns.

Whereas state-regulated marijuana is age-gated, with mandated quality assurance and quality control testing, and is sold in child-resistant packaging, IHDC products fall largely outside of these regulatory controls. This presents added risks associated with pesticides, residual solvents, and/or other contaminants from chemical synthesis, inconsistent and inaccurate potency labeling¹⁹⁸ while being widely available in smoke shops, gas stations, and through e-commerce.¹⁹⁹ The HHS Rescheduling Memo minimally recognized:

[S]ome hemp-derived CBD products may contain Δ9-THC or other cannabinoids in amounts sufficient to produce drug effects more associated with marijuana and may or may not be legally within the definition of marijuana. It is acknowledged that their widespread use may contribute to the epidemiological data on marijuana use that is discussed in Factors 4, 5, and 6 of this scientific and medical evaluation.²⁰⁰

A substantial body of research, including scientific publications and news coverage, has highlighted the serious health risks and impacts stemming from the ease of access to intoxicating hemp cannabinoids.²⁰¹ The accurate understanding of

¹⁹⁷ NPRM, 89 Fed. Reg. at 44,622.

¹⁹⁸ M. ElSohly et al., *Chemical Composition and Properties of Delta-8 THC*, J. OF CANNABIS RSCH. (2021).

¹⁹⁹ AMERICANS FOR SAFE ACCESS, 2022 STATE OF THE STATES REPORT: AN ANALYSIS OF MEDICAL CANNABIS ACCESS IN THE UNITED STATES (Feb. 2023), <https://www.safeaccessnow.org/sos22>.

²⁰⁰ HHS Basis for Rec. at 3.

²⁰¹ Dana G. Smith, *How Delta-8 THC Works, and Why Experts Are Worried About It*, N.Y. TIMES, July 1, 2022, updated July 25, 2022 <https://www.nytimes.com/2022/07/01/well/mind/delta-8-thc-marijuana.html>. The article discusses the rise in popularity and the potential health risks associated with delta-8 THC, a cannabinoid derived from hemp, which has psychoactive effects similar to delta-9 THC. Liz Essley-Whyte *Hemp Gummies Are Sending Hundreds of Kids to Hospital*, WALL ST. J., Dec. 19, 2023, <https://www.wsj.com/health/healthcare/hemp-gummies-are-sending-hundreds-of-kids-to-hospitals->

the size and scope of the IHDC market, especially following the passage of the 2018 Farm Bill, reveals a significantly larger impact on epidemiological data than previously recognized. Specifically, synthetic tetrahydrocannabinols derived from hemp, such as delta-8 THC, have been shown to contribute overwhelmingly to adverse event data, including severe illnesses and hospitalizations, particularly among children.²⁰²

Delta-8 THC, one of over 100 cannabinoids produced by the genus *Cannabis sativa* L., has received the most attention. Due to the naturally low and commercially unviable levels of delta-8 THC found in hemp, additional chemicals are utilized to convert plentiful cannabinoids in hemp such as CBD into delta-8 THC.²⁰³ Other cannabinoids either not present in the *Cannabis sativa* L. plant in any amount or found only in commercially unviable levels also require synthetic conversion. Specifically, THC-O-acetate and HHC have a similar chemical structure and pharmacological activity to those cannabinoids contained in the *Cannabis sativa* L. plant but can only be obtained synthetically. As such, DEA has confirmed their status as THC's falling outside of the definition of hemp and they are, therefore, controlled under schedule I.²⁰⁴

The synthesis process involves several chemical reactions, including acid-catalyzed isomerization, to convert CBD into delta-8 THC. These processes can produce various unknown by-products due to incomplete or side reactions.²⁰⁵ Also, residual solvents used in the extraction and purification processes, such as heptane or toluene, can remain in the final product if not adequately removed, and are

[00ab0224?mod=Searchresults_pos2&page=1](#). The article highlights the alarming increase in hospitalizations of children due to accidental ingestion of hemp-derived gummies containing delta-8 THC. Jen Christensen 'A false sense of security': Experts say delta-8 THC products can still be dangerous, CNN, <https://www.cnn.com/2024/02/09/health/delta-8-thc-cannabis-wellness/index.html>.

²⁰² CDC Health Alert Network Advisory, *Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events* (2021), https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_451.pdf; CDC; Am's. Poison Ctrs., *Delta-8 THC* (June 30, 2024), <https://www.aapcc.org/track/delta-8-thc>; A. Higginbotham, *Legislature moves to ban unregulated cannabis, delta-8 THC products from NJ stores*, NJ.COM (June 6, 2023) <https://www.nj.com/marijuana/2023/06/legislature-moves-to-ban-unregulated-cannabis-delta-8-thc-products-from-nj-stores.html>.

²⁰³ ElSohly, *supra* note 198. This structural difference affects its binding affinity to cannabinoid receptors in the brain, leading to slightly different psychoactive effects compared to delta-9 THC. M. ElSohly et al., *Safety and Toxicology of Delta-8 THC*, INT'L J. OF CANNABIS SCI. (2021) Dr. El Sohly's findings from in market testing of product the variability in product quality and purity, particularly in unregulated markets, poses significant health risks.

²⁰⁴ Two Letters issued by Terrence L Boos, Ph.D., Chief Drug & Chemical Evaluation Section Diversion Control Division, one related to status of HHC <https://www.cannabislegalhighlights.com/wp-content/uploads/sites/47/2023/06/DEA-THCA-and-HHC-letter.pdf>, and the other related to status of THC-O, <https://www.greenmarketreport.com/wp-content/uploads/2023/02/DEA-THCO-response-to-Kight.pdf>.

²⁰⁵ FDA, 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC, <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc> (last visited July 19, 2024).

potentially toxic and harmful if ingested or inhaled.²⁰⁶ Residual acid catalysts, if not properly neutralized and removed, can pose serious health risks.²⁰⁷ Many of these by-products and contaminants have not been studied extensively for their safety, have been brought to market without the traditional vetting associated with foods, drugs, cosmetics, and dietary supplements, and may pose significant health risks.

In May 2022, FDA expressed clear concerns:

Some manufacturers may use potentially unsafe household chemicals to make delta-8 THC through this chemical synthesis process. Additional chemicals may be used to change the color of the final product. The final delta-8 THC product may have potentially harmful by-products (contaminants) due to the chemicals used in the process, and there is uncertainty with respect to other potential contaminants that may be present or produced depending on the composition of the starting raw material. If consumed or inhaled, these chemicals, including some used to synthesize hemp cannabinoids and the by-products created during synthesis, can be harmful.

Manufacturing of delta-8 THC products may also occur in uncontrolled or unsanitary settings, which may lead to the presence of unsafe contaminants or other potentially harmful substances.²⁰⁸

Although FDA attributes these concerns squarely to IHDCs, HHS has minimized the effects hemp-related adverse events have on the marijuana reporting data.

The regulatory gray area enabling widespread sale and distribution of delta-8 THC and other synthetically derived “hemp” tetrahydrocannabinol products lacks comprehensive safety evaluations or consistent oversight that is common with regulated marijuana. Nonetheless, IHDC products are available in a variety of forms including, but not limited to, candy, cookies, breakfast cereal, chocolate, gummies, vape cartridges (carts), dabs, shatter, topicals, smokable hemp sprayed with THC extract, distillate, tinctures, and infused beverages. These product form factors often copycat traditional consumer packaged goods, specifically those that are attractive to children like Doritos, Sour Patch Kids, and Oreos.²⁰⁹ These IHDC products are

²⁰⁶ Michael Geci et al., The Dark Side of Cannabidiol: The Unanticipated Social and Clinical Implications of Synthetic Δ8-THC 8 Cannabis & Cannabinoid Rsch. 270–82 (April 2023), <https://pubmed.ncbi.nlm.nih.gov/36264171/>.

²⁰⁷ *Id.*

²⁰⁸ FDA, 5 Things to Know, *supra* note 205.

²⁰⁹ Press Release, FDA, FTC Continue Joint Effort to Protect Consumers Against Companies Illegally Selling Copycat Delta-8 THC Food Products (July 16, 2024), <https://www.fda.gov/news-events/press-announcements/fda-ftc-continue-joint-effort-protect-consumers-against-companies-illegally-selling-copycat-delta-8>.

dominating sales, reportedly accounting for as much as 44% of all U.S. hemp cannabinoid sales.²¹⁰ The ease of access, which includes products that are widely available via e-commerce²¹¹ and in retail stores such as smoke shops, convenience stores, and wellness centers, has prompted Attorneys General across the country to issue warnings for consumer protection and awareness.²¹²

The explosive growth captured in a Whitney Economics report estimates the total market demand for the sale of these hemp cannabinoid products to be \$28 billion,²¹³ currently eclipsing the size of the U.S. marijuana market. Additional reporting has found global delta-8 THC products valued at \$2.35 billion in 2021 and expected to scale at a compounding annual growth rate of 21.5% from 2022 to 2030.²¹⁴ Within the United States, the market for delta-8 THC and other hemp-derived cannabinoids has increased a staggering 1,283% in just under three years.²¹⁵ Sales data confirms the widespread availability and consumption of these products. The growth trajectory confirms that unregulated intoxicating hemp-derived markets continue to outpace their regulated counterparts. That is unwelcome news for those who purport to care about public safety.

Both FDA and CDC²¹⁶ have raised concerns about the safety of delta-8 THC products in particular, noting numerous adverse event reports including hallucinations, vomiting, tremors, anxiety, dizziness, confusion, and loss of consciousness.²¹⁷ FDA received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022.²¹⁸ Of these 104 adverse events, 77% involved adults, 8% involved pediatric

²¹⁰ FDA, *5 Things to Know*, *supra* note 205.

²¹¹ Examples of leading e-commerce websites for intoxicating hemp: [Delta Extracts](#); [3Chi](#); [Cookies Hemp & CBD](#); [Hometown Hero](#); [Mood](#) and the [Hemp Doctor](#) (last visited on July 17, 2024). Many of these websites do not require age verification. Many feature marketing seemingly designed to be attractive to children. And most proclaim the federally legal status of products including new novel cannabinoids that do not exist naturally, including THCP, THCO and HHC as well as delta-8 and delta-9 as result of synthetic conversion.

²¹² Tony Lange, *21 Attorneys General call on Congress to address 'intoxicating hemp' products in the Farm Bill*, CANNABIS BUS. TIMES, Mar. 21, 2024, <https://www.cannabisbusinesstimes.com/news/21-attorneys-general-congress-farm-bill-hemp-delta8/>.

²¹³ Beau Whitney, *2023 U.S. National Cannabinoid Report – Executive Summary*, WHITNEY ECONS. (Oct. 26, 2023), <https://whitneyeconomics.com/blog/us-national-cannabinoid-report---executive-summary>.

²¹⁴ GRAND VIEW RESEARCH, CANNABIDIOL MARKET SIZE, SHARE & TRENDS ANALYSIS REPORT BY SOURCE TYPE (HEMP, MARIJUANA), BY SALES TYPE (B2B, B2C), BY END-USE (MEDICAL, PERSONAL USE), BY REGION, AND SEGMENT FORECASTS, 2024–2030, <https://www.grandviewresearch.com/industry-analysis/cannabidiol-cbd-market>.

²¹⁵ BRIGHTFIELD DATA, [THE STATE OF DELTA-8: HEMP-DERIVED THC UPDATE \(Nov. 2023\)](#), https://cdn.prod.website-files.com/596691afde3c5856d866ae50/654e66ad036ff9f10c5b38fe_Hemp-Derived%20THC%20Update_Report_Final.pdf.

²¹⁶ CDC, Health Alert Network Advisory, *supra* note 202.

²¹⁷ FDA issues strong warning on cannabis products containing delta-8 THC, UCLA HEALTH (May 6, 2022); FDA, *5 Things to Know*, *supra* note 205.

²¹⁸ FDA, *5 Things to Know*, *supra* note 205.

patients less than 18 years of age, and 15% did not specify age. Further, 55% required medical intervention ranging from evaluation by emergency medical personnel to hospital admission, and 66% described adverse events including, but not limited to, hallucinations, vomiting, tremors, anxiety, dizziness, confusion, and loss of consciousness after ingesting food products (e.g., brownies, gummies) containing delta-8 THC.

In response, FDA Principal Deputy Commissioner Janet Woodcock, M.D., expressed in public statement:

The FDA is very concerned about the growing popularity of delta-8 THC products being sold online and in stores nationwide. These products often include claims that they treat or alleviate the side effects related to a wide variety of diseases or medical disorders, such as cancer, multiple sclerosis, chronic pain, nausea and anxiety It is extremely troubling that some of the food products are packaged and labeled in ways that may appeal to children.²¹⁹

In a series of warning letters to hemp-cannabinoid manufacturers beginning in 2019, FDA delineated concerns that included issues of companies selling products that “people may confuse for traditional foods or beverages,” emphasizing those that are appealing to children.²²⁰ Concerns were also raised about products containing cannabinoids other than CBD, including delta-8, delta-9, cannabigerol, and cannabitol, explaining that these products containing an unapproved food additive or ingredient are adulterated and their sale violates the Federal Food, Drug, and Cosmetic Act (“FDCA”).²²¹

The nascent nature of the IHDC marketplace and the lack of rigorous safety data and quality control measures exacerbates these concerns. Poison control centers have documented thousands of exposure cases related to delta-8 THC, with significant increases in recent years.²²² In an effort to better track and analyze the increasing number of delta-8 THC exposures, the American Association of Poison

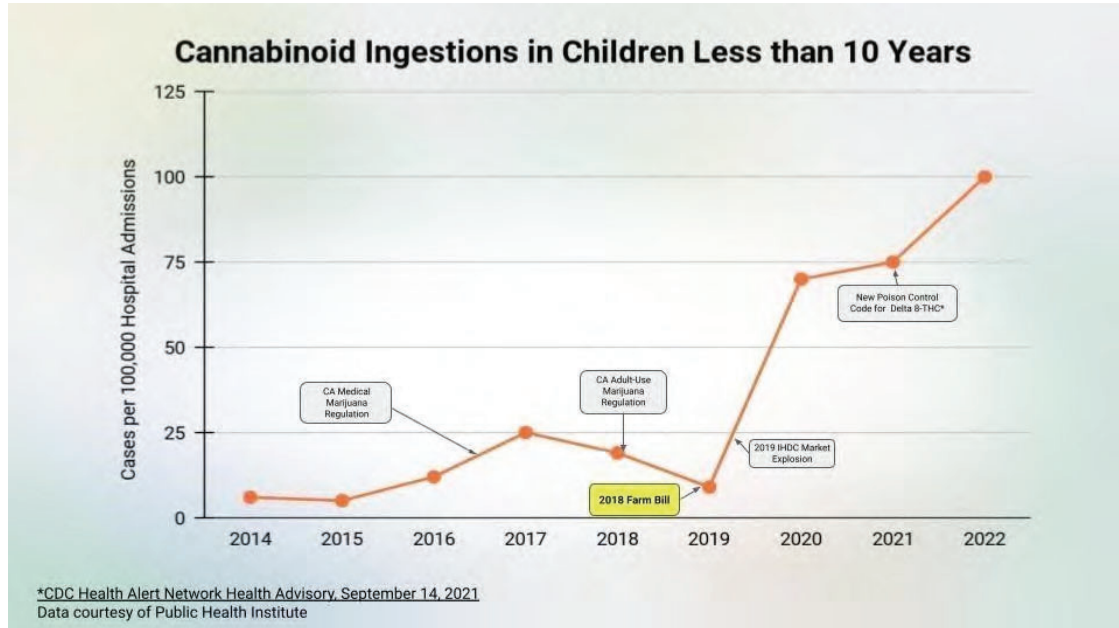
²¹⁹ News Release, FDA, FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products (May 4, 2022), <https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products>.

²²⁰ FDA Constituent Update, FDA Warns Companies for Illegally Selling Food and Beverage Products that Contain CBD (Nov. 21, 2022), <https://www.fda.gov/food/cfsan-constituent-updates/fda-warns-companies-illegally-selling-food-and-beverage-products-contain-cbd>.

²²¹ *Id.* Examples of these warning letters include the ones FDA issued to 11-11-11 Brands, Naturally Infused LLC, Newhere Inc dba CBDFX, Infusionz LLC, and CBD American Shaman, LLC, each of which are available here: <https://www.fda.gov/food/cfsan-constituent-updates/fda-warns-companies-illegally-selling-food-and-beverage-products-contain-cbd>.

²²² News Release, Shauna Devitt, Administrator, Am’s. Poison Ctrs., America’s Poison Centers Releases The Annual Report of the National Poison Data System® (NPDS) (Jan. 18, 2024), <https://piper.filecamp.com/uniq/P2nQIZD7062jaPpg.pdf>.

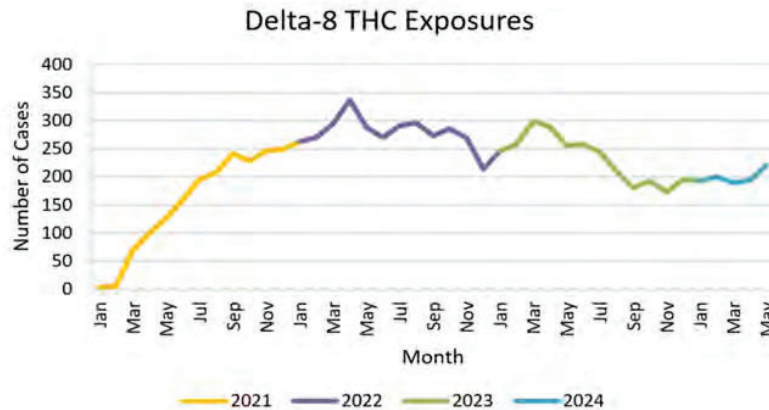
Control Centers integrated a new product code for delta-8 products into its National Poison Data System (“NPDS”) in 2021. The uptick in delta-8 incidences corresponds and correlates directly with the proliferation of IHDC product sales, **not** with legal, regulated marijuana product sales. In data from California depicted in the graph below, hospital admissions from cannabinoid ingestions *decreased* in the period directly following marijuana regulation but *increased* precipitously after the 2018 Farm Bill and the introduction of IHDCs into the marketplace.



The national poison control centers have managed 8,985 delta-8-related exposure cases from the new product code inception in 2021 to 2024.²²³ For the current year (as of the end of May 2024), poison control centers have managed 997 cases related to delta-8 THC exposure, averaging around 200 cases per month.²²⁴

²²³ Am’s. Poison Ctrs., *Delta-8 THC*, *supra* note 202.

²²⁴ *Id.*



The graph illustrates the peak increase in 2022 with 3,358 delta-8 THC exposure cases, which appeared alongside 130 instances of minor cannabinoid exposures.²²⁵ The findings of the 2023 MTF survey published in the Journal of the American Medical Association, and funded by the National Institutes of Health, found 11.4% of 12th graders admitted to using delta-8 products.²²⁶ An Illinois resident who used medical marijuana for anxiety purchased delta-8 THC at a convenience store, thinking it was similar to her trusted medical marijuana. This led to severe drug toxicity, resulting in hospitalization for a month and subsequent outpatient rehab with hallucinations.²²⁷ Events such as these must be properly attributed in the evaluation of adverse reporting data, not merely treated like a cursory rounding error.

Even though delta-8 THC has a specific code in the NPDS, the data for cannabinoid exposure does not distinguish between different sources—hemp or marijuana. This results in mixed data that incorrectly links delta-8 THC incidents with marijuana. This data mix-up affects reports for all cannabinoids, not just delta-8 THC.²²⁸ The mapping of cannabinoid exposures, regardless of their origin, correlates with the rise of hemp-derived cannabinoid products, particularly in states without regulated marijuana programs.²²⁹

In sum, IHDC products have contributed significantly to increased levels of abuse and harm that are incorrectly attributed to marijuana. The commingling of

²²⁵ Gummin et al., *supra* note 183.

²²⁶ Harlow et al., *supra* note 79.

²²⁷ *Increasing number of people hospitalized due to poisoning from Delta-8 weed*, FOX32 CHI. (July 9, 2024, 9:23pm CDT), <https://www.yahoo.com/news/increasing-number-people-hospitalized-due-022317500.html>.

²²⁸ CDC, Health Alert Network Advisory, *supra* note 202. Details the rise in adverse events linked to delta-8 THC and underscores the challenge of source-agnostic data.

²²⁹ Tennessee Poison Control Center reported a significant number of calls regarding delta-8 THC exposure. Specifically, in 2022, the center received 115 calls. This represents a significant increase of 3x from the prior year. Most of these incidents affect children under the age of 6. Grace King, *Tennessee Poison Center seeing 'alarming' increase in calls about delta-8 and children*, 10NEWSNBC (updated Mar. 17, 2023, 9:59 PM EDT).

data on cannabinoid exposures, without distinguishing by source, results in misleading safety profiles and inaccurate classification of adverse event reporting. This is exacerbated in states without regulated marijuana programs, where IHDC products dominate the cannabinoid market.

The current regulatory framework for cannabinoids, particularly delta-8 THC, highlights significant gaps in data accuracy and safety oversight. DOJ's proposed rescheduling of marijuana to schedule III does not account for the core issues related to the proliferation of intoxicating hemp-derived cannabinoid products. These products, which include delta-8 THC, delta-9 THC, and other synthetic tetrahydrocannabinols, often exceed potency levels allowed in state-regulated marijuana markets and are not subjected to the same rigorous testing and safety standards.

The data on abuse potential is distorted due to the comingling of reporting data from marijuana and unregulated synthetic IHDC products that generally lack the very base levels of regulation common to and successful in all marijuana programs: testing requirements, age gating, and child-resistant packaging. This conflation skews the understanding of the true risks and effects associated with marijuana.

2. Stigma Stemming from Marijuana's Long-standing Schedule I Misclassification Has Skewed Relevant Abuse-Potential Data.

Marijuana's schedule I classification has always been controversial, but it has never been about science. When Congress passed the CSA in 1970, it placed marijuana in schedule I only tentatively. It did so not because of what science *proved* or even suggested about the plant but because of what it *didn't* prove.²³⁰ Assistant Secretary of Health Dr. Roger Egeberg made the initial recommendation.²³¹ As he put it, “‘Since there is little’—‘still a considerable void in our knowledge of the plant and effects of the active drug contained it in it, our recommendation is marijuana be retained within Schedule I at least until the completion of certain studies now underway to resolve the issue.’”²³² Along with this preliminary classification, Congress established a “Commission on Marihuana and

²³⁰ See also *Mixed Signals: The Administration's Policy on Marijuana, Part Two: House Hearing Before the Subcommittee on Government Operations of the Committee on Oversight and Government Reform*, 113th Cong., 2d Sess. (Mar. 4, 2014) (“Mixed Signals Hearing”) (“[Assistant Secretary of Health], Dr. Egeberg [(the man who initially recommended placing marijuana in schedule I)] said, ‘Since there is little’—‘still a considerable void in our knowledge of the plant and effects of the active drug contained it in it, our recommendation is marijuana be retained within Schedule I at least until the completion of certain studies now underway to resolve the issue.’ So not because of sound science ... [b]ut because of its absence, its absence of science, because they never completed the studies, looked at the studies, nor got involved there that it was schedule—Schedule I.”). A transcript of the entire hearing is available at <https://www.govinfo.gov/content/pkg/CHRG-113hhrg91225/html/CHRG-113hhrg91225.htm>.

²³¹ *Id.*

²³² *Id.*; see also *Gonzales v. Raich*, 545 U.S. 1, 14 (2005) (same).

Drug Abuse,”²³³ and provided it \$1 million to study the legal, scientific, and medical aspects of marijuana use.²³⁴ The Commission was to report back to Congress and the President within two years with “appropriate recommendations for legislation and administrative actions.”²³⁵

President Nixon appointed Gov. Raymond P. Shafer of Pennsylvania, a former prosecutor with a “law-and-order” reputation, to run the Commission.²³⁶ According to Oval Office tapes declassified in 2002, Nixon told Shafer he wanted a report that would blur the distinction between marijuana and hard drugs. As the Commission’s investigation was getting underway in May 1971, Nixon told his aide, “I want a goddamn strong statement about marijuana. Can I get that out of this son-of-a-bitching, uh, domestic council? I mean one on marijuana that just tears the ass out of them.”²³⁷ According to Nixon, the “Jews” were to blame for the rising popularity of legalization.²³⁸ “Every one of the bastards that are out for legalizing marijuana is Jewish,” Nixon complained. “What the Christ is the matter with the Jews, Bob, what is the matter with them? I suppose it’s because most of them are psychiatrists, you know, there’s so many, all the greatest psychiatrists are Jewish. By god, we are going to hit the marijuana thing, and I want to hit it right square in the puss. I want to find a way of putting more on that.”²³⁹

When Shafer eventually brought the Commission’s report to the White House, it concluded that marijuana was safer than alcohol, and recommended ending prohibition in favor of a public health approach.²⁴⁰ Unsurprisingly, Nixon did not follow that recommendation. Recounting this history, Nixon’s aide John Ehrlichman revealed that the real reason marijuana landed in schedule I was not because of science but because it served the Nixon Administration’s overtly racist political agenda:

Look, we understand we couldn’t make it illegal to be young or poor or black in the United States. But we could criminalize their common pleasure. We understand that drugs were not the health problem we were making them

²³³ See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513 § 601, 84 Stat. 1236 (Oct. 27, 1970).

²³⁴ *Id.* § 601(d), (e).

²³⁵ *Id.* § 601(f).

²³⁶ Fred Gardner, *The Shafer Commission Report (1972)*, BEYONDTHC.COM (June 2012), <https://beyondthc.com/the-shafer-commission-report-1972/>.

²³⁷ David Downs, *The Science behind the DEA’s Long War on Marijuana*, SCI. AM. (Apr. 19, 2026), <https://www.scientificamerican.com/article/the-science-behind-the-dea-s-long-war-on-marijuana/>.

²³⁸ See Mixed Signals Hearing, *supra* note 230.

²³⁹ Downs, *supra* note 237.

²⁴⁰ U.S. COMM’N ON MARIJUANA & DRUG ABUSE, MARIJUANA: A SIGNAL OF MISUNDERSTANDING; FIRST REPORT (1972), <https://www.ojp.gov/ncjrs/virtual-library/abstracts/marihuana-signal-misunderstanding-first-report-national-commission>.

out to be. But it was such a perfect issue for the Nixon White House, we couldn't resist it We knew we were lying about the health effects on marijuana. We knew we were lying about that. But this is what we were doing to win the election. And it worked.²⁴¹

This initial misclassification has systematically warped our collective understanding of marijuana ever since and in two interrelated ways. First, it has resulted in a massively exaggerated sense of the harms associated with marijuana use. As DEA itself has emphasized, law enforcement organizations and the labs they use to gather the law-enforcement data relevant to the abuse-potential analysis tend to prioritize cases involving drugs in stricter schedules.²⁴²

This same schedule I stigma has caused the federal government to invest massively in studying the *negatives* of marijuana use almost exclusively. A recent study of how the federal government spends research dollars revealed that of the more than \$1 billion the National Institute on Drug Abuse doled out for marijuana research from 2000 to 2018, the vast majority was spent “to research [marijuana] misuse and its negative effects.”²⁴³ Thus, by placing marijuana in the strictest of the CSA's schedules, the Nixon Administration guaranteed that marijuana would be the focus of more negative attention and related data-gathering than substances in less-restrictive schedules. For decades now, this sustained and outsized focus on the adverse effects and consequences of marijuana use has skewed the data in a way that makes marijuana look worse than it actually is, compared to substances in less-restrictive schedules. And it's been a significant waste of federal tax dollars.

Second, marijuana's schedule I status simultaneously *blocks* scientists from studying its benefits, including its potential medical utility. In testimony before the House Subcommittee on Health, Committee on Energy and Commerce, NIDA Director Dr. Nora Volkow recently described the extraordinary challenges researchers face when seeking to study schedule I substances, contrasting them with the dramatically more relaxed regulations that apply to substances in schedules II through V:

Even experienced researchers have reported that obtaining a new Schedule I registration [from DEA under 21 U.S.C.

²⁴¹ See Mixed Signals Hearing, *supra* note 230.

²⁴² See HHS Hrg., Criteria for Scheduling Recommendations Under the Controlled Substances Act at 172 (Sept. 11, 1997) (“[W]hen a police officer submits a variety of drugs for analysis in order to work a case, what that laboratory will do is they will look at the drugs and determine what the schedule of each drug is. They will find that, ‘I have a drug here schedule IV, I have a drug here that’s in schedule that’s in III, I have a drug here in schedule II. Well, the only thing I really need to do is the drug that’s in schedule II to get the conviction.’.... So, if you don’t analyze it, you’re not going to see it. It’s a tremendous amount of work to go to these laboratories and get that data.”).

²⁴³ Cathleen O’Grady, *Cannabis research database shows how U.S. funding focuses on harms of the drug*, *Sci.* (Aug. 27, 2020), <https://www.science.org/content/article/cannabis-research-database-shows-how-us-funding-focuses-harms-drug>.

823(f)], adding new substances to an existing registration, or getting approval for research protocol changes is time consuming. Unlike for Schedule II through V substances, new and amended Schedule I applications are referred by the DEA to the HHS for a review of the protocol and a determination of the qualifications and competency of the investigator. This review is often in addition to other reviews of the proposed research and investigator, such as the federal grant review process, the FDA Investigational New Drug (IND) application review process, and Institutional Review Board and Institutional Animal Care and Use Committee reviews. Establishing the security infrastructure needed to conduct Schedule I research can be expensive and may need to be duplicated for each registrant working within a single research department. Researchers have also reported that there is a lack of clarity in some of the registration requirements and variability in their interpretation, which complicates and adds time to the process. For example, researchers report inconsistency in the guidance they have received on whether one individual can work under the registration of another, whether separate registrations are needed for each of an investigator's research sites within the same campus, whether a manufacturing registration is needed to create final dosage formulations for research purposes, among other issues. Researchers have reported that sometimes these challenges impact Schedule I research and deter or prevent scientists from pursuing this critical work.²⁴⁴

A 2017 National Academies study examined the problem of schedule I research barriers in the marijuana context specifically.²⁴⁵ After describing “[t]he substantial layers of bureaucracy that emerge from marijuana’s Schedule I categorization,” the authors explain that marijuana’s schedule I classification has stifled “research on the health effects of cannabis and cannabinoids . . . in the United States, leaving patients, health care practitioners, and policy makers without the evidence they need to make sound decisions regarding the use of cannabis and cannabinoids.” Their

²⁴⁴ *The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances: Presented to Testimony before the Subcommittee on Health, Committee on Energy and Commerce, U.S House of Representatives* (Dec. 2, 2021) (testimony of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse), <https://nida.nih.gov/about-nida/legislative-activities/testimony-to-congress/2021/the-overdose-crisis-proposal-to-combat-illicit-fentanyl>.

²⁴⁵ NAT'L ACADS, THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS (2017).

conclusion is ominous (and obviously right): “This lack of evidence-based information on the health effects of cannabis and cannabinoids poses a public health risk.”

In sum, the Nixon Administration placed marijuana in schedule I not because of the science but despite it. From then on, straight through to the present day, marijuana’s misclassification as a schedule I drug has warped the abuse-potential data from both directions—ensuring an outsized focus on the negatives of marijuana use while simultaneously stymieing efforts to study marijuana’s benefits. The fact that the data so overwhelmingly supports HHS’s conclusion that marijuana has an abuse potential less than substances in schedules I and II despite all this is, therefore, remarkable. While we support HHS’s conclusion, the warping effects of intoxicating hemp data and marijuana’s schedule I status that we have highlighted here demonstrate that if HHS’s analysis is even remotely inaccurate, it is only because it almost certainly overstates marijuana’s abuse potential.

III. Additional Considerations Lend Still Further Support to HHS’s Abuse-Potential Findings.

Three additional factors that HHS did not focus on but that nevertheless are important to the abuse-potential analysis lend additional support to HHS’s conclusion that marijuana has an abuse potential less than substances in schedules I and II.

First, the same legislative history that DEA and HHS have relied on for framing the abuse-potential analysis also emphasizes the importance of the substance’s use in suicides and suicide attempts to the overall analysis.²⁴⁶ HHS’s recommendation and evaluation never mentions marijuana use being linked to suicides or suicide attempts but never factors the lack of any such evidence into its final conclusion regarding marijuana’s abuse potential. Given the overwhelming number of suicides and attempted suicides involving schedule I and II drugs such as fentanyl and heroin, respectively, this consideration adds additional support to HHS’s conclusion that marijuana has a lower abuse potential than substances in schedules I and II.

Second, the legislative history also emphasizes the importance of the economics of enforcement and regulation of the substance to the abuse-potential analysis.²⁴⁷ While HHS did not consider this factor, it, too, supports HHS’s conclusion regarding abuse potential. The federal government invests massively in efforts to enforce against and regulate schedule I and II drugs such as heroin, fentanyl, and Adderall. Combatting opioid-use disorder and the related overdose epidemic, for example, remains a top priority for the federal government generally and DEA specifically. Marijuana, by contrast, is a perennial *low* priority for federal enforcement and regulation. Indeed, in each fiscal year since 2015, Congress has

²⁴⁶ See, H.R. REP. NO. 91-1444, *supra* note 88, at 34.

²⁴⁷ See S. REP. NO. 813, 91st Cong., 1st Sess., at 15 (1969) (“In reaching his decision, the Attorney General should consider the economics of regulation and enforcement attendant to such a decision.”).

adopted an appropriations rider that prohibits DOJ from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana.²⁴⁸ The mismatch between marijuana's strict scheduling classification on the one hand and, on the other hand, the federal government's apparent disinterest in enforcement of schedule I (or even schedule II) restrictions against marijuana is a tacit acknowledgment that the risks and harms associated with marijuana do not actually warrant schedule I or II treatment.

Third, the existence of effective and robust state-level enforcement and regulation of marijuana likely provides at least a partial explanation for the federal government's lack of urgency when it comes to marijuana enforcement and regulation. Historically, DEA has emphasized the role that state-level controls play in ameliorating a substance's potential for abuse. The case of [¹⁸F]FP-CIT is one example.²⁴⁹ In addressing that substance's abuse potential, DEA observed that although it presented risks of stimulant effects in animal studies, stringent regulation at the federal, state, and local levels would address much of that risk.²⁵⁰ Because [¹⁸F]FP-CIT would be "distributed and handled under a highly regulatory environment," DEA looked past the fact that the substance was a derivative of schedule II cocaine.²⁵¹

As discussed throughout our comments, marijuana is and will continue to be highly regulated throughout the United States through, among other things, DEA federal manufacturer registration requirements, FDA clinical study requirements, and state licensing of growers, processors, and dispensaries. These tight regulatory controls are sufficient to ensure that the potential for abusing marijuana remains low. More specifically, as HHS noted in its recommendation that DEA reschedule marijuana to schedule III:

[M]ore than 30,000 HCPs are authorized to recommend the use of marijuana for more than six million registered patients, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States. For several jurisdictions, these programs have been in place for several years, and include features that

²⁴⁸ *E.g.*, Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, § 531, 138 Stat. 25 (2024); Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 531, 136 Stat. 4459, 4561 (2022); *see* CONG. RSCH. SERV., R44782, THE EVOLUTION OF MARIJUANA AS A CONTROLLED SUBSTANCE AND THE FEDERAL-STATE POLICY GAP at 26 & n.159 (updated Apr. 7, 2022) (collecting laws).

²⁴⁹ *See* Schedules of Controlled Substances: Removal of [[FN18]F]FP-CIT From Control, 87 Fed. Reg. 70,715, 70,716 (Nov. 21, 2022) (codified at 21 C.F.R. §1308).

²⁵⁰ *Id.*

²⁵¹ *Id.*

actively monitor medical use and product quality characteristics of marijuana dispensed.²⁵²

Despite the widespread availability of marijuana throughout the United States—not only to the six million registered state medical marijuana patients but also to the estimated 23.25 million regular consumers of adult-use marijuana—HHS *still* found that the public health risks posed by marijuana are relatively lower than those posed by most other comparator drugs, and more specifically, low compared to drugs in schedules I and II.

Having reviewed every scheduling decision DEA and its predecessor agency have made in the CSA's history, we can certify that neither agency has *ever* overruled a single HHS determination of a substance's abuse potential under the CSA.²⁵³ In the vast majority of cases, DEA's entire abuse-potential analysis amounts to a few sentences or, at most, a few paragraphs. Given the extraordinary thoroughness of HHS's review and analysis of the abuse-potential issue in this proceeding, a DEA decision to break from that pattern, which it has sustained uniformly now for over half a century, would be shocking. After all, the principle that courts and agencies must "[t]reat like cases alike" is "the central precept of justice."²⁵⁴

Prohibitionists attempting to make a correlation between reclassifying marijuana to schedule III and increased youth use are misinformed, at best. While our country's youth should not be consuming intoxicating products, including caffeine, nicotine, marijuana, alcohol, or opioids, rescheduling marijuana will do nothing to exacerbate the problem of youth access. And as we explain in detail below, it is the state-regulated marijuana marketplace that is taking measures to prevent youth use. The illicit market and the market for unregulated synthetic IHDC products share none of those protections. So, the prohibitionist's attempt to draw a straight line between rescheduling and increased youth use simply blinks reality. That fiction does not serve the youth that we are trying to protect, nor does it create an environment where we can reasonably unearth solutions to shared public policy challenges.

a. Potential for Abuse: Trends in Youth Usage Support a Schedule III Classification

In assessing the abuse potential of any drug, FDA and its Center for Drug Evaluation and Research currently do not discretely consider whether a drug or substance has a disproportionate impact on youth.²⁵⁵ However, an abuse-potential assessment reviews whether there is widespread non-therapeutic use of a drug or a

²⁵² HHS Basis for Rec. at 24.

²⁵³ A list of those decisions with their respective Federal Register citations is available at <https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>.

²⁵⁴ H.L.A. HART, THE CONCEPT OF LAW 164 (3d ed. 2012) (quotation marks omitted); *see also* Aristotle, *Ethica Nicomachea* V.3.1131a–1131b (W.D. Ross trans. 1925) ("[T]hings that are alike should be treated alike.").

²⁵⁵ FDA GUIDANCE, *supra* note 90.

substance.²⁵⁶ While access and use by minors may be instructive in a drug's abuse potential, it is not dispositive. However, we must of course consider any potential negative health outcomes for minors. Fortunately, trends in relevant data lead to encouraging deductions, and existing regulations at the state level have proven effective in preventing youth use and associated harms within the state-regulated marijuana industry, reinforcing that a schedule III reclassification is sound public policy.

In December 2023, the chief of the epidemiological research branch of NIDA acknowledged that adult use legalization had not resulted in increased youth usage, nor had it resulted in changes in perceived availability of marijuana.²⁵⁷ This is supported by data confirming that legal, regulated businesses are adhering to the law and not selling or marketing to underage individuals, as evidenced by Colorado licensed operators' 99% compliance rate for preventing underage sales.²⁵⁸ Updates in data sources used by HHS as a basis for its August 2023 recommendation, including the YRBSS and MTF, support a similar conclusion.

i. Update to Youth Risk Behavior Surveillance System Data

The Proposed Rule relies on data from the YRBSS through 2019 in concluding marijuana should be reclassified to schedule III. Since HHS concluded its eight-factor analysis, YRBSS data has been updated with two additional years of data to include 2020 and 2021, representing the first post-pandemic analysis of such data.²⁵⁹

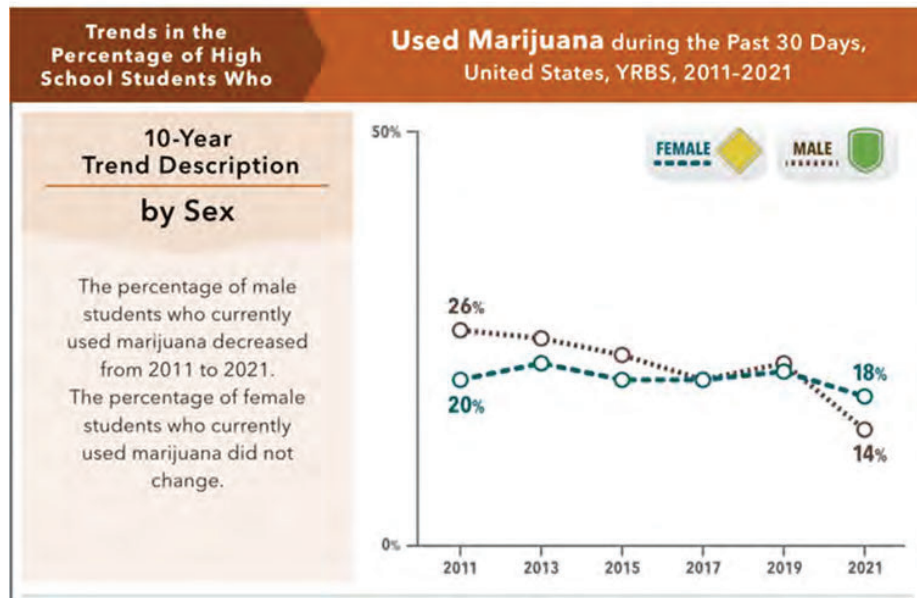
The most recent update to that 2021-2022 data indicates that current marijuana use among high schoolers has *decreased* below pre-pandemic levels.

²⁵⁶ *Id.* at 4.

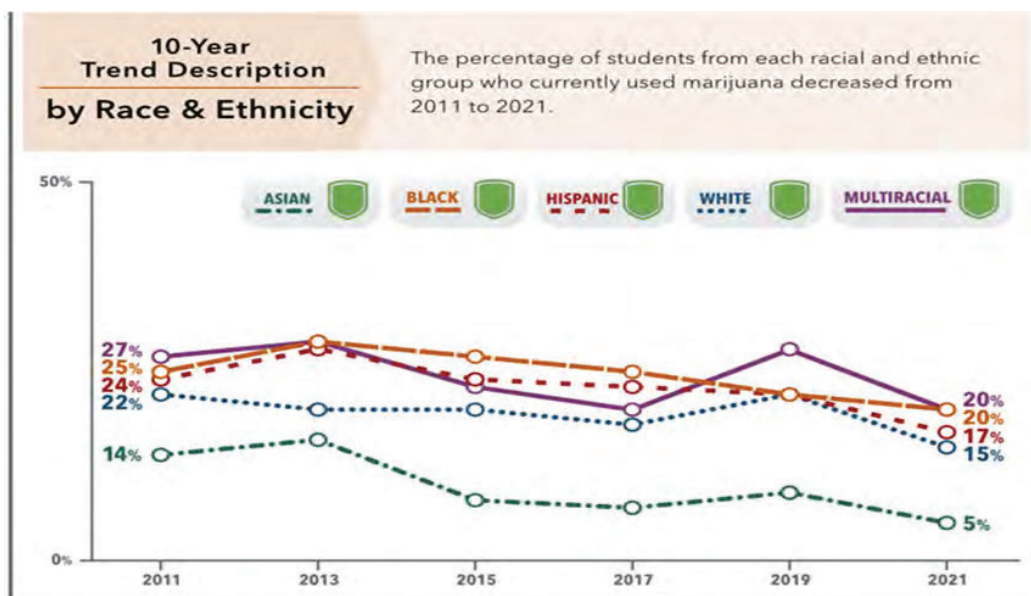
²⁵⁷ Kyle Jaeger, *State Marijuana Legalization Has 'Not Really Impacted' Teen Use, Federal Official Says As New Youth Survey Shows Stable Trends*, MARIJUANA MOMENT (Dec. 13, 2023), <https://www.marijuanamoment.net/state-marijuana-legalization-has-not-really-impacted-teen-use-federal-official-says-as-new-youth-survey-shows-stable-trends/>.

²⁵⁸ Colo. Dep't of Revenue, [CDOR:MED Underage Sales Dashboard \(google.com\)](https://cdor.med.underage.sales.dashboard.google.com).

²⁵⁹ 2023 YRBSS data that will contain information from 2022 will not be addressed here as it is expected to be released in the late fall of 2024, well after the comment period for this docket closes.

Fig. 1²⁶⁰

In 2021, 16% of high schoolers reported using marijuana in the last 30 days, compared to 23% of high school students who drank alcohol and 18% of high school students who used electronic vapor products/e-cigarettes. The 2021 data indicated that marijuana use among high schoolers in the past 30 days is *down* when compared to 2019 data.

Fig. 2²⁶¹

²⁶⁰ CDC, YOUTH RISK BEHAVIOR SURVEY, *supra* note 124.

²⁶¹ *Id.* at 34.

ii. Update to Monitoring the Future Data and Healthy Kids Colorado Survey (2023)

MTF, another database used by HHS in its basis for its schedule III recommendation, indicated that in 2023 marijuana use remained stable and below pre-pandemic levels for all three grades surveyed, with 8.3% of 8th graders, 17.8% of 10th graders, and 29% of 12th graders reporting marijuana use in the past year.²⁶² The 2023 survey was also the first time MTF reviewed data on the use of delta-8 THC, which 11.4% of 12th graders reported using in the past year.²⁶³

Although the Proposed Rule indicates that delta-8 THC and other synthetic IHDCs are outside the scope of the scheduling change, and despite delta-8 THC being a federally illegal synthetic substance (not within the legal definition of hemp and illegal under many state laws),²⁶⁴ this psychoactive compound found in the *Cannabis sativa L.* plant is often available through retail outlets that do not have the same standards for age verification as state-licensed marijuana dispensaries do.²⁶⁵ Unsurprisingly, delta-8 THC usage is higher in states that do not have legalized and regulated marijuana programs.²⁶⁶ State-regulated programs serve to protect youth—unregulated IHDC products simply do not.

The decrease in marijuana use among youth in legal, regulated markets is best illustrated by the continued decline in teen marijuana use in Colorado since the state legalized medical marijuana 20 years ago. The Healthy Kids Colorado Survey (2023) shows a steady decline in youth-reported use of marijuana at 12.8% in 2023, down from 13.3% in 2021 and 25.5% in 2019.²⁶⁷ Importantly, the same Healthy Kids Survey shows that high school students believe it is harder to get marijuana under a regulated system than it was before Colorado legalized—54.9% of high school students believed marijuana was easy to get in 2013, compared to 40.4% in 2023.²⁶⁸ Colorado's data set, as the first state to legalize marijuana, is particularly instructive given the long span of data proving that legalization has not increased consumption

²⁶² <https://monitoringthefuture.org/wp-content/uploads/2023/12/mtf2023.pdf>.

²⁶³ *Id.*

²⁶⁴ DEA, DRUG & CHEMICAL EVALUATION SECTION PRESENTATION (May 4, 2023), [Emerging Trends \(usdoj.gov\): Schedules of Controlled Substances: Rescheduling of Marijuana \(dea.gov\)](#), at 83 (stating that “synthetic THC will remain in schedule I.”).

²⁶⁵ News Release, NIH, *Delta-8-THC Use Reported by 11% of 12th Graders in 2023*, (Mar. 12, 2024), <https://www.nih.gov/news-events/news-releases/delta-8-thc-use-reported-11-12th-graders-2023#:~:text=There%20is%20no%20federal%20minimum.gas%20stations%20and%20convenience%20stores> (indicating that there is no federal minimum age for purchase of delta-8 products).

²⁶⁶ Harlow, *supra* note 79.

²⁶⁷ Colo. Dep't Pub. Health & Env't, [Healthy Kids Colorado Survey Dashboard | Department of Public Health & Environment](#) (2023), (marking the lowered percentage of students reporting marijuana use since Colorado legalized marijuana in 2014); Evan Kruegel, *Biannual Colorado survey shows decrease in youth marijuana use*, 9NEWSNBC (updated June 20, 2024, 7:09 PM MDT), [Colorado survey shows decrease in youth marijuana use | 9news.com](#).

²⁶⁸ Healthy Kids Colorado Survey Dashboard, *supra* note 267.

patterns among youth. Colorado's regulated marijuana program includes ID checks for sales (which has a compliance rate of 99%),²⁶⁹ monitoring of youth use, and allocation of resources toward successful youth prevention and education campaigns. Other states have followed Colorado's lead with similar success.

iii. Studies Supporting Trends in Federal Surveys

Reassuring trends related to youth use of marijuana are bolstered by research of the American Medical Association ("AMA") and JAMA Pediatrics, which have indicated that neither adult use marijuana legalization nor the opening of retail stores in U.S. states led to increases in youth use.²⁷⁰ The AMA references data from 47 states, looking at responses from 898,271 teens, and found that adult use marijuana laws led to *lower* odds of any marijuana use.²⁷¹

These findings on adult use legalization provide further support for a 2019 JAMA Pediatrics study indicating that medical marijuana laws did not increase youth usage and that marijuana may be more difficult to obtain when a state has implemented frameworks that require proof of age.²⁷² In fact, as the Healthy Kids Colorado Survey demonstrates, rates of marijuana use among high school students has continued to decrease since legalization and remains below the national average.²⁷³ Additionally in Colorado, the perception of disapproval of marijuana use continues to go up, with more than 70% of Colorado high schoolers saying they disapprove of someone their age using marijuana.²⁷⁴

Unsurprisingly, national trends showing flat or decreasing youth usage post-legalization are consistent with Colorado-specific data. Specifically, trends in New York, Oregon, and Washington²⁷⁵ show no significant increase in youth usage of

²⁶⁹ CDOR:MED Underage Sales Dashboard, *supra* note 258.

²⁷⁰ D. Mark Anderson et al., *Recreational Marijuana Laws and Teen Marijuana Use, 1993-2021*, JAMA PSYCHIATRY (Apr. 24, 2024), <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2818043>.

²⁷¹ Rebekah Levine Coley et al., *Recreational Marijuana Legalization, Retail Sales, and Adolescent Substance Use Through 2021*, JAMA PEDIATRICS (Apr. 15, 2024), <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2817566>.

²⁷² D. Mark Anderson et al., *Association of Marijuana Laws with Teen Marijuana Use*, JAMA PEDIATRICS (July 8, 2019), <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2737637>. See also, D. Mark Anderson, et. al., *Association of Marijuana Legalization With Marijuana Use Among US High School Students, 1993-2019*, JAMA NETW., OPEN., (Sep. 7, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783850> (finding there were no significant associations between enactment of RMLs or MMLs and marijuana use among high school students).

²⁷³ Healthy Kids Colorado Survey Dashboard, *supra* note 267.

²⁷⁴ *Id.*

²⁷⁵ Myduc Ta et al., *Trends and Characteristics in Marijuana Use Among Public School Students — King County, Washington, 2004–2016*, 68 MORBIDITY & MORTALITY WEEKLY REP. 845–50 (Oct. 4, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6839a3.htm?s_cid=mm6839a3_w; Healthy Kids Colorado Survey Dashboard, *supra* note 267.

marijuana following legalization.²⁷⁶ Aiding in this decline is the fact that marijuana regulation, rather than strict prohibition, implements effective barriers to youth access. States with legal marijuana programs have implemented strict age verification processes that prevent minors from obtaining marijuana or marijuana products.²⁷⁷

iv. Adverse Mental Health Outcomes in Youth

Although longitudinal data shows trends of decreased or neutral youth usage after marijuana legalization, schedule III substances are not completely without risk. Marijuana, like any other substance controlled or uncontrolled (i.e., tobacco and alcohol), has the potential for adverse consequences on developing brains, including the potential to affect youth mental health conditions.

Literature is mixed on the impact of marijuana use on the development of psychosis,²⁷⁸ so more research is critical to understand this risk factor. Further, some of the available studies on the impact that marijuana usage has on mental health, including psychosis, conflate correlation and causation without appropriately identifying whether those with pre-existing psychiatric disorders are more predisposed to use marijuana or it is the marijuana use itself that contributes to adverse mental health consequences.²⁷⁹

²⁷⁶ Jennifer A. Bailey et al., *Effects of Marijuana Legalization on Adolescent Marijuana Use Across 3 Studies*, AM. J. OF PREVENT. MED., Vol. 64, 361–367, (Mar. 2023), <https://www.sciencedirect.com/science/article/abs/pii/S0749379722004913>.

²⁷⁷ James C. Fell et al., *What is the likelihood that underage youth can obtain marijuana from licensed recreational marijuana outlets in California, a state where recreational marijuana is legal*, 82 J. SAFETY RSCH. 102–11, (Sept. 2022), <https://www.sciencedirect.com/science/article/abs/pii/S002243752200055X?via%3Dihub> (identifying 100% of California dispensaries visited required age verification); *See also*, Carla J. Berg et al., *Cannabis retailer marketing strategies and regulatory compliance: A surveillance study of retailers in 5 US cities*, 143 Addictive Behaviors (Aug. 2023), <https://www.sciencedirect.com/science/article/abs/pii/S0306460323000916?via%3Dihub> (identifying 90% verified age compliance across five cities); Colo. Dep't of Revenue, *Industry Wide Bulletin 22-04* (Aug. 9, 2022), https://sbg.colorado.gov/sites/sbg/files/220809_IB22-04_Underage_Compliance_Check_Bulletin.pdf (identifying 98% compliance rate in age verification).

²⁷⁸ Conor H. Murray et al., *Adolescents are more sensitive than adults to acute behavioral and cognitive effects of THC*, 47 NEUROPSYCHOPHARMACOLOGY 1331–38 (Feb. 2, 2022), <https://www.nature.com/articles/s41386-022-01281-w#~:text=Adolescents%20were%20more%20sensitive%20to%20behavioral%20and%20cognitive%20effects%20of,finding%20adolescents%20more%20sensitive%20to%20behavioral%20and%20cognitive%20effects%20of%20THC> (finding adolescents more sensitive to behavioral and cognitive effects of THC); *see also* Andre J McDonald et al., *Age-dependent association of marijuana use with risk of psychotic disorder*, PSYCH. MED. (May 22, 2024), <https://pubmed.ncbi.nlm.nih.gov/38775165/> (suggesting youth marijuana use is associated with psychotic disorders), *c.f.*, Ricardo E. Carrión et al., *Recreational cannabis use over time in individuals at clinical high risk for psychosis: Lack of associations with symptom, neurocognitive, functioning, and treatment patterns*, 328 PSYCHIATRY RSCH. (Oct. 2023), <https://www.sciencedirect.com/science/article/abs/pii/S0165178123003700?via%3Dihub> (finding no association with marijuana use and negative neurocognitive outcomes).

²⁷⁹ *See e.g.*, Sarah Kanana Kiburi et al., *Cannabis use in adolescence and risk of psychosis: Are there factors that moderate this relationship? A systematic review and meta-analysis*, 42 SUBSTANCE ABUSE 527–42 (Feb. 22, 2021), <https://pubmed.ncbi.nlm.nih.gov/33617756/> (finding age of onset of use, concurrent use, age, genetic factors and childhood trauma may all play a role in the development of marijuana use and psychosis).

Studies have occasionally found associations between marijuana use and psychiatric disorders, but the existing scientific data does not establish a clear causal relationship. In other words, people with psychiatric disorders use marijuana at greater rates, but there are no studies indicating that marijuana itself was the cause of their psychiatric disorders. Researchers also point out that people with psychiatric disorders use all drugs at greater rates than the general public.²⁸⁰

While a preponderance of the evidence indicates marijuana does not cause psychiatric disorders, it can trigger or exacerbate symptoms in people with existing conditions, and some research suggests youth face greater risk of adverse effects than adults.²⁸¹ For example, a study published in JAMA Psychiatry in 2021 found reliable evidence that shared familial/genetic risk factors and/or reverse causation substantially contributed to the marijuana-schizophrenia association, and that genetic risks that increase the probability of both marijuana use and schizophrenia (“confounding”) explain some of the association.²⁸² Another study published in JAMA Psychiatry in 2022 found a reverse association—that genetic predisposition for schizophrenia leads to higher likelihood of marijuana use. It also found that environmental stressors (childhood adversity, urbanicity, and obstetric and pregnancy complications, among others) played a significant role.²⁸³ Notably, a 2023 JAMA study found that “state medical and recreational [marijuana] policies were not associated with a statistically significant increase in rates of psychosis-related health outcomes. As states continue to introduce new marijuana policies, continued evaluation of psychosis as a potential consequence of state marijuana legalization may be informative.”²⁸⁴ A schedule III classification appropriately recognizes potential risks of psychological and physiological dependence while opening pathways for additional research.

²⁸⁰ *Common Comorbidities with Substance Use Disorders Research Report*. Bethesda (MD): National Institutes on Drug Abuse (Apr. 2020), <https://www.ncbi.nlm.nih.gov/books/NBK571451/>.

²⁸¹ Marta Di Forti et al., *The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study*, 6 THE LANCET 427–36 (May 2019), [https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366\(19\)30048-3/fulltext?hsenc=p2ANqtz-9JK34foO9hQj2Vll5Xe9Wbytxg5TtK5pTIWpB226Q85QfdD1oi5_mQnSx-gGbVeiV6_KSy](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30048-3/fulltext?hsenc=p2ANqtz-9JK34foO9hQj2Vll5Xe9Wbytxg5TtK5pTIWpB226Q85QfdD1oi5_mQnSx-gGbVeiV6_KSy); Gabriella Gobbi et al., *Association of Cannabis Use in Adolescence and Risk of Depression, Anxiety, and Suicidality in Young Adulthood: A Systematic Review and Meta-analysis* 76 JAMA PSYCHIATRY 426–34 (2019), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2723657>; Marco Colizzi & Robin Murray, *Cannabis and psychosis: what do we know and what should we do?*, 212 BRIT. J. PSYCHIATRY 195–96 (Mar. 20, 2018), <https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/cannabis-and-psychosis-what-do-we-know-and-what-should-we-do/D09D5E6B7A77D475B3BD63D81462BF7A>.

²⁸² Nathan A. Gillespie & Kenneth S. Kendler, *Use of Genetically Informed Methods to Clarify the Nature of the Association Between Cannabis Use and Risk for Schizophrenia*, 78 JAMA PSYCHIATRY 467–68 (Nov. 4. 2020), <https://doi.org/10.1001/jamapsychiatry.2020.3564>.

²⁸³ Bochao Danae Lin et al., *Nongenetic Factors Associated With Psychotic Experiences Among UK Biobank Participants Exposome-Wide Analysis and Mendelian Randomization Analysis*, 79 JAMA PSYCHIATRY 857–68 (July 20, 2022), <https://doi.org/10.1001/jamapsychiatry.2022.1655>.

²⁸⁴ Holly Elser et al., *State Cannabis Legalization and Psychosis-Related Health Care Utilization*, 6 JAMA NETWORK (Jan. 25, 2023), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800728>.

The risk profile of comparable substances in schedules II-V that are often prescribed to youth and have recognized risks to youth health illustrate that schedule III is the most appropriate classification for marijuana given its “currently accepted medical use in treatment in the United States” and relative risk profile. By way of example, psychotropic drugs are medications that affect the brain and behavior, such as antidepressants, stimulants, antipsychotics, and sedatives. They are often prescribed to treat various mental health conditions such as attention-deficit/hyperactivity disorder, depression, anxiety, bipolar disorder, schizophrenia, and autism spectrum disorder. However, the use of psychotropic drugs in treating children and adolescents has been a controversial issue, as there are concerns about the drugs’ safety, efficacy, and long-term effects.²⁸⁵ In spite of concerns, they are still widely prescribed to young people and effective for treatment.

b. Potential for Abuse: Current Industry Safeguards Preventing Unauthorized Youth Access and Diversion

A responsible marijuana industry can ensure that marijuana and marijuana products do not end up in the hands of minors (under 21 years of age). In states with adult-use programs, purchasers of marijuana must be at least 21 years old. While many states allow minors to participate in medical programs, the standards for participation are often quite rigorous, including receiving opinions from multiple health care practitioners, limiting conditions to an approved list, and setting time limits on approvals for participation in marijuana marketplaces.

Current state-regulated marijuana programs impose additional safeguards to prevent unauthorized underage access, underage exposure, and diversion, including:

- A. Tracking marijuana from seed to sale, usually through specific state-mandated track and trace software systems;
- B. Requiring all dispensaries to verify the age of patients and/or consumers before allowing them to purchase marijuana; and
- C. Imposing product, packaging, labeling, and marketing and advertising rules and restrictions to prevent the exposure and promotion of marijuana products to minors.

State Tracking Systems. One of the primary ways state-regulated marijuana programs prevent diversion of marijuana into unregulated markets and into the hands of minors is through the usage of traceability systems, also known as “track and trace.” Almost all state-regulated marijuana programs require the use of a traceability system, with the exception of Arizona’s medical and adult-use marijuana

²⁸⁵ Florentia Kaguelidou & Eric Acquaviva, *Safety of Psychotropic Drugs in Children and Adolescents*, PHARMACOVIGILANCE IN PSYCHIATRY 257–83 (Dec. 8, 2015), https://doi.org/10.1007/978-3-319-24741-0_13; see also Gabriel P.A. Costa et al., *Efficacy of topiramate in reducing second-generation antipsychotic-associated weight gain among children: A systematic review and meta-analysis*, 26 DIABETES, OBESITY & METABOLISM 2292–2304 (Mar. 13, 2024), <https://doi.org/10.1111/dom.15543>.

programs and Maine's medical marijuana program.²⁸⁶ Those programs instead impose strict inventory reporting requirements that serve similar purposes.²⁸⁷

Traceability systems such as Metrc and BioTrack allow licensed marijuana businesses and state regulators to monitor marijuana products from their initial source seed or plant through growth phases, processing steps, and until the final sale to consumers.²⁸⁸ Each packaged product includes a tag or ID number, which gives state regulators visibility into every stage of the product's development and production. These systems also track wholesale transfers, product sales to end consumers, and product returns, destruction, and disposal.²⁸⁹ This detailed tracking system helps secure the regulated market against illicit products and provides state regulators with the necessary information to monitor inventory and prevent marijuana from reaching minors. The illicit market and unregulated synthetic IHDC products share none of these protections.

Age Verification. To prevent minors from accessing and being exposed to regulated marijuana, state-regulated programs require medical and adult-use dispensaries to verify the age of patients and consumers before making a sale.²⁹⁰ At a minimum, these programs require the visual inspection of a government-issued identification. Other states impose even stricter age verification requirements.²⁹¹ For instance, New Jersey requires that dispensaries maintain a log documenting that the examination of photographic identification and confirmation of legal age has

²⁸⁶ See *Metrc: Our Partners*, METRC, <https://www.metrc.com/partners/> (last visited July 17, 2024); *BioTrack Legislation Location*, BIOTRACK, <https://biotrack.com/legislation-location/united-states/> (last visited July 17, 2024); *Marijuana Central Reporting System*, WASHINGTON STATE LIQUOR AND MARIJUANA BOARD, <https://lcb.wa.gov/ccrs> (last visited July 17, 2024); *Illinois Marijuana Tracking System*, <https://etk.icts.illinois.gov/etk-icts-prod/login.request.do> (last visited June 28, 2024); CT PRESCRIPTION MONITORING PROGRAM SYSTEM, <https://connecticut.pmpaware.net/login> (last visited June 28, 2024); UTAHID, <https://evs.utah.gov/login.sso.submit.do> (last visited June 28, 2024); VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS PRESCRIPTION MONITORING SYSTEM, <https://virginia.pmpaware.net/login> (last visited June 28, 2024); OHIO BOARD OF PHARMACY, <https://ohio.pmpaware.net/login> (last visited June 28, 2024); NORTH DAKOTA BOARD OF PHARMACY, <https://northdakota.pmpaware.net/login> (last visited June 28, 2024); GEORGIA DEPARTMENT OF PUBLIC HEALTH PRESCRIPTION DRUG MONITORING PROGRAM, <https://georgia.pmpaware.net/login> (last visited June 28, 2024); MISSISSIPPI PRESCRIPTION MONITORING PROGRAM, <https://mississippi.pmpaware.net/login> (last visited June 28, 2024); IOWA CODE ANN. § 124E.11.

²⁸⁷ See *Adult Use Marijuana: Filing Requirements*, ARIZ. DEP'T OF REVENUE, <https://azdor.gov/transaction-privilege-tax/adult-use-marijuana/filing-requirements#:~:text=After%20a%20taxpayer%20obtains%20an,monthly%20on%20the%20TPT%20return> (last visited July 17, 2024); *Dep't of Admin & Fin. Servs. Off. of Cannabis Pol'y, Inventory Tracking*, MAINE.GOV, <https://www.maine.gov/dafs/ocp/node/295> (last visited July 17, 2024); *Getting Started Guide - Metrc Inventory Tracking System*, MAINE.GOV, https://www.maine.gov/dafs/ocp/sites/maine.gov.dafs.omp/files/inline-files/Getting_Started_Guide-Metrc_Inventory_Tracking_System-AUMP.pdf (last visited July 17, 2024).

²⁸⁸ See *What is Metrc?*, METRC, <https://www.metrc.com/wp-content/uploads/2021/10/2-Metrc-2-Pager-FNL.pdf> (last visited July 17, 2024); *Government Traceability Solutions*, BIOTRACK, <https://biotrack.com/solutions/government-seed-to-sale-solutions/>.

²⁸⁹ See *What Is Metrc?*, METRC, *supra* note 288; *Government Traceability Solutions*, BIOTRACK, *supra* note 289.

²⁹⁰ See MICH. ADMIN. CODE R. 420.104; OR. ADMIN. R. 845-025-2820; MO. CODE REGS. ANN. tit. 19, § 100-1.180.

²⁹¹ See N.J. ADMIN. CODE § 17:30-14.3; NEV. MARIJUANA COMPLIANCE BD., REG. 7.015; MO. CODE REGS. ANN. tit. 19, § 100-1.180.

occurred; Nevada and Missouri employees are required to use ID-scanning technology to scan the barcodes on consumer and patient identifications to confirm their age and identification validity before selling marijuana.²⁹²

Licensed dispensaries have access to various technologies that can help with age verification and ensure that minors cannot gain access. As mentioned above, ID-scanning technologies are typically used when consumers and patients first enter a dispensary's security checkpoint and play a crucial role in preventing underage sales by detecting underage and fraudulent identifications.²⁹³ Furthermore, even when not required by state rules and regulations, licensed dispensaries often use ID-scanning technology as an additional measure. One study found that 32% of the 50 dispensaries surveyed in California scanned customers' IDs before allowing them to enter, even though the state does not require it.²⁹⁴ Moreover, point-of-sale systems in dispensaries are able to assist with ID verification and help prevent underage access. These systems can be set up to show warnings when an underage ID is scanned and can stop a sale by preventing a minor from checking in at the dispensary.²⁹⁵

Studies have demonstrated that state regulations aimed at preventing underage access to regulated marijuana are effective and that dispensaries comply with these laws.²⁹⁶ For example, the Oregon Liquor and Cannabis Commission ("OLCC") runs a minor decoy program through which underage individuals try to purchase alcohol and marijuana at licensed dispensaries and liquor stores.²⁹⁷ Statistics from the OLCC's minor decoy program from 2018 to the present indicate that licensed dispensaries consistently prevent underage sales at higher rates than liquor stores.²⁹⁸ A similar 2022 study conducted in California yielded similar results.²⁹⁹ In that study, participants attempted to enter 47 dispensaries across the state without identification and 100% of the dispensaries turned the customers away, granting them entry only upon presenting their valid identification.³⁰⁰ The Colorado Department of Revenue's Marijuana Enforcement Division has also regularly sent

²⁹² N.J. ADMIN. CODE §17:30-14.3; NEV. MARIJUANA COMPLIANCE BD., REG. 7.015; MO. CODE REGS. ANN. tit. 19, § 100-1.180.

²⁹³ See *ID Scanners for Dispensaries*, IDSCAN.NET, (last visited July 17, 2024).

²⁹⁴ Fell, *supra* note 277.

²⁹⁵ *Manage check-in settings for scanned IDs*, DUTCHIE (last visited July 17, 2024), <https://support.dutchie.com/hc/en-us/articles/21194045779091-Manage-check-in-settings-for-scanned-ID>;

Flowhub Greet, FLOWHUB, <https://flowhub.com/product/greet> (visited July 17, 2024).

²⁹⁶ *Minor Decoy Operations*, OR. LIQUOR & MARIJUANA COMM'N, <https://www.oregon.gov/olcc/pages/minor-decoy-operations.aspx> (last visited July 17, 2024); Fell, *supra* note 278.

²⁹⁷ *Minor Decoy Operations*, *supra*, note 296.

²⁹⁸ *Id.*

²⁹⁹ Fell, *supra* note 277.

³⁰⁰ *Id.*

underage operatives to attempt to purchase marijuana at dispensaries across the state.³⁰¹ Each year nearly all Colorado dispensaries were compliant and consistently refused to sell to the underage operatives.³⁰² The dispensary compliance rates in 2022 and 2023 were particularly high at 99%, suggesting that these regulations could become more effective over time as dispensaries become accustomed to strictly enforcing them.³⁰³ The illicit market and unregulated synthetic IHDC marketplace have no age verification protections in place.

Packaging and Labeling. To prevent underage exposure and access to marijuana products in the regulated market, licensed businesses are required to adhere to strict marijuana packaging and labeling rules. Many state-regulated programs prohibit the use of imagery and labels that might appeal to children such as cartoons, toys, and any variation of the word “candy” on product packaging.³⁰⁴ For example, Washington prohibits cartoons, bubble type, and other cartoon-like fonts from appearing on the packaging, while Nevada goes even further by banning images of cartoon characters, mascots, action figures, balloons, and toys.³⁰⁵ Additionally, edible products in Michigan cannot be associated with or have cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors.³⁰⁶

To prevent underage individuals from consuming marijuana, states also require that marijuana products be packaged in child-resistant and tamper-evident containers.³⁰⁷ Most states, at a minimum, apply some variation of the pre-existing federal standards established by the Poison Prevention Packaging Act of 1970. Other states impose even stricter requirements on marijuana businesses. For example, Oregon requires the packaging to be tested by a qualified third-party package testing firm prior to sale.³⁰⁸ California requires single-serving bottles to have “a pry-off, metal crown, cork-style bottle cap” and for single servings of marijuana intended to be inhaled or marijuana products that are applied topically to be packaged in plastic

³⁰¹ Colorado Department of Revenue Marijuana Enforcement Division, “Underage Compliance Check Bulletin” (August 9, 2022), https://sbg.colorado.gov/sites/sbg/files/220809_IB22-04_Underage_Compliance_Check_Bulletin.pdf.

³⁰² *Colorado MED Underage Sales Dashboard*, Colorado Department of Revenue Marijuana Enforcement Division (accessed July 2, 2024), https://lookerstudio.google.com/u/0/reporting/b7952e72-713b-4880-b4e2-01370b36ebab/page/p_tc49hpi4zc.

³⁰³ *Id.*

³⁰⁴ See e.g., COLO. CODE REGS. § 212-3-3-720; WASH. ADMIN. CODE § 314-55-105; NEV. REV. STAT. § 678B.520; NEV. MARIJUANA COMPLIANCE BD., REG. 12.015; MICH. ADMIN. CODE R 420.403.

³⁰⁵ See e.g., WASH. ADMIN. CODE § 314-55-155; NEV. MARIJUANA COMPLIANCE BD., REG. 12.015; MD. CODE REGS. 10.62.29.01.

³⁰⁶ See MICH. MARIJUANA REGUL. AGENCY, MARIJUANA-INFUSED EDIBLES: ENFORCEMENT GUIDANCE (August 2, 2021), https://www.michigan.gov/-/media/Project/Websites/cra/bulletin/Marijuana-Infused_Edibles_Bulletin_-_080221.pdf.

³⁰⁷ See e.g., OR. ADMIN R. 845-025-7020; OR. REV. STAT. ANN. § 475C.612 (West); MD. CODE REGS. 10.62.29.0; MD. CODE REGS. 10.62.24.01.

³⁰⁸ See OR. ADMIN R. 845-025-7020.

packaging that is at least four milliradians thick and heat-sealed without an easy-open tab, dimple, corner, or flap.³⁰⁹ In addition, states including Colorado and Maryland require the packaging to include warnings about the risks associated with marijuana, especially for children and pregnant women.³¹⁰

Marijuana edible products that could easily be mistaken as commercially sold candy often appear in the unregulated market.³¹¹ In contrast, state-regulated markets have imposed specific restrictions for edibles to prevent edible marijuana products and their packaging from appealing to minors.³¹² At least 14 states have bans against the production of edibles that mimic commercially available food.³¹³ For example, Nevada prohibits packaging that resembles popular candy brands or products primarily consumed by or marketed to children.³¹⁴ Michigan prohibits edibles from being in the shape of a human, animal, or fruit or from resembling commercially sold candy like Reese's Peanut Butter Cups or Sour Patch Kids.³¹⁵ Additionally, Massachusetts forbids edibles from being sold in the shape of humans, animals, fruits, or sporting equipment.³¹⁶ Similarly, Alabama only permits edibles to be sold in a "cuboid" or a "gelatinous cube" shape.³¹⁷ These restrictions on product appearance, labeling, and packaging aim to prevent confusion between marijuana products and non-intoxicating ones, reducing the risk of underage exposure. The illicit market does not have standardized packaging at all. And the the unregulated synthetic IHDC market actually uses packaging that replicates children's brands to appeal to youth.³¹⁸

Advertising and Marketing Restrictions. State-regulated marijuana programs have rules and regulations in place to limit underage exposure to

³⁰⁹ Julia A. Dilley et al., *Trends and Characteristics of Manufactured Cannabis Product and Cannabis Plant Product Exposures Reported to US Poison Control Centers, 2017-2019*, 4 JAMA NETWORK OPEN (2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780068>.

³¹⁰ *E.g.*, COLO. CODE REGS. § 212-3-3-1010; MD. CODE REGS. 10.62.29.0; MD. CODE REGS. 10.62.24.01; N.Y. COMP. CODES & REGS. tit. 9 § 113.12; MICH. ADMIN. CODE R. 420.504.

³¹¹ See *Consumer alert issued in California for illegal edibles packaged to look like popular snacks*, KTLA 5 NEWS (Oct. 28, 2021, 2:34PM PDT), <https://ktla.com/news/local-news/consumer-alert-issued-in-california-for-illegal-edibles-packaged-to-look-like-popular-snacks/>; Ginny Monk, *Sour Patch or Stoney Patch? Parents warned about edible pot packaging*, CT INSIDER (Oct. 27, 2021), <https://www.ctinsider.com/business/article/Sour-Patch-or-Stoney-Patch-Parents-warned-about-16568445.php>.

³¹² MICH. MARIJUANA REGUL. AGENCY, *supra* note 306; 935 MASS. CODE REGS. 500.150; ALA. CODE § 20-2A-3.

³¹³ Dilley, *supra* note 309.

³¹⁴ NEV. MARIJUANA COMPLIANCE BD., REG. 12.015.

³¹⁵ See MICHIGAN MARIJUANA REGUL. AGENCY, *supra* note 306.

³¹⁶ 935 MASS. CODE REGS. 500.150.

³¹⁷ ALA. CODE § 20-2A-3.

³¹⁸ Press Release, FTC, FTC Sends Cease and Desist Letters with FDA to Companies Selling Edible Products Containing Delta-8 THC in Packaging Nearly Identical to Food Children Eat (July 5, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-sends-cease-desist-letters-fda-companies-selling-edible-products-containing-delta-8-thc>.

marijuana advertising and marketing. Some states, such as Hawaii and New Hampshire, have broad restrictions that prohibit marijuana companies from using common modes of advertising, including radio, print media, social media, and the internet.³¹⁹ Many other states impose specific advertising restrictions to minimize underage exposure to marijuana marketing; for example, numerous state programs do not allow marijuana to be advertised in a particular medium, like a magazine or radio advertisement, unless there is data showing the vast majority of the intended audience is of legal age to consume marijuana.³²⁰ Internet advertisements on marijuana websites are also regulated through “age gate” mandates that require visitors to confirm their age before gaining access to the website.³²¹

Some states impose restrictions on where marijuana advertisements can be placed to limit exposure to minors. For example, in Washington and Nevada, marijuana advertisements cannot be displayed within 1,000 feet of a school, playground, recreation center, childcare center, public park, library, or arcade, or on or in a private vehicle, public transit vehicle, bus stop, or other transit-related locations.³²² State regulators also moderate the content of marijuana advertisements so that they do not appeal to minors. For example, many states do not allow marijuana advertisements to contain cartoons, toys, or the likeness of popular characters.³²³ Likewise, Maryland prohibits marijuana advertisements from targeting minors; Nevada and Washington also require all advertisements to carry warning verbiage that the product is “only for use by adults 21 or over.”³²⁴ The illicit market and unregulated synthetic IHDC products share none of these protections.

In short, while youth should not be consuming intoxicating products of any kind, it is the state-regulated marijuana industry that is taking painstaking efforts to make certain that minors are denied access. And the notion that rescheduling marijuana to schedule III somehow correlates to a likelihood that our youth will have increased access to marijuana is completely nonsensical and unsubstantiated.

Marijuana Has a Currently Accepted Medical Use in Treatment in the United States

In developing its scientific and medical evaluation and scheduling recommendation, HHS “updated” its approach to assessing “currently accepted medical use in treatment in the United States” (“CAMU”), recognizing a new two-

³¹⁹ See e.g., HAW. CODE R. § 11-850-145; N.H. CODE ADMIN. R. HE-C 402.3.

³²⁰ See CAL. CODE REGS. tit. 4, § 15040; COLO. CODE REGS. § 212-3-3-720; MICH. ADMIN. CODE R 420.507; OR. ADMIN. R. 845-025-8060.

³²¹ See e.g., OR. ADMIN. R. 845-025-8060; OHIO ADMIN. CODE 3796:5-7-01; CAL. CODE REGS. tit. 4, § 15041.

³²² WASH. ADMIN. CODE § 314-55-155; NEV. REV. STAT. § 678B.520; NEV. MARIJUANA COMPLIANCE BD., REG. 6.120.

³²³ See NEV. REV. STAT. § 678B.520; NEV. MARIJUANA COMPLIANCE BD., REG. 6.120; CAL. CODE REGS. tit. 4, § 1504; WASH. ADMIN. CODE §314-55-155.

³²⁴ See Md. Code Regs. 10.62.34.08; Md. Code Ann., Health-Gen. § 13-3313.1; Nev. Marijuana Compliance Bd., Reg. 12.070; Wash. Admin. Code § 314-55-155.

part standard.³²⁵ Part 1 asks whether “[t]here exists widespread, current experience with medical use of the substance by HCPs operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine.”³²⁶ Factors supporting such a determination include:

1. Whether a substantial number of HCPs have gained clinical experience with at least one specific medical use of the substance under existing and implemented state authorized programs;
2. Whether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance; and
3. Whether an HCP’s clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer-term toxicities and potential harms of the substance when used under medical supervision.³²⁷

If the Part 1 analysis of the Office of the Assistant Secretary for Health (“OASH”) “supports the finding that marijuana has at least one CAMU in the United States,”³²⁸ then FDA proceeds to Part 2, assessing whether “[t]here exists some credible scientific support for at least one of the medical uses for which Part 1 is met.”³²⁹

Applying this standard to marijuana, the OASH undertook the Part 1 analysis and found that more than 30,000 HCPs are certified to recommend marijuana for more than six million registered patients under various state medical marijuana regimes.³³⁰ The OASH concluded that this “constitut[ed] widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States.”³³¹ The OASH emphasized that “[f]or several jurisdictions, these programs have been in place for several years, and include features that actively monitor medical use and product quality characteristics of marijuana dispensed.”³³² “Taken together,” it concluded that “the findings from Part 1 warrant an FDA assessment under Part 2 of [HHS’s] CAMU approach to determine if there exists credible scientific support for the use of marijuana for at

³²⁵ Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, Re: Part 1 Analysis at 1 (July 17, 2023) (“HHS Part 1 Analysis Memo”).

³²⁶ *Id.* at 2.

³²⁷ *Id.*

³²⁸ *Id.* at 1

³²⁹ *Id.* at 2.

³³⁰ *Id.* at 6.

³³¹ *Id.*

³³² *Id.*

least one of the medical conditions [the OASH identified during the Part 1 investigation].”³³³

After conducting the Part 2 review, FDA concluded that there does, in fact, exist “some credible scientific support for the use of marijuana in at least one of the indications for which there is widespread current experience with its medical use in the United States, as identified under Part 1 of the CAMU test.”³³⁴ In conducting its Part 2 analysis, FDA assessed marijuana’s use as medicine for seven indications, “based in part on OASH’s findings under Part 1 of the CAMU test and in part on FDA’s own analysis of the landscape in which marijuana is currently used medically, including information from state-authorized programs on how and to what extent marijuana is being utilized for medical purposes.”³³⁵ Those seven indications were anorexia, anxiety, epilepsy, inflammatory bowel disease, nausea and vomiting, pain, and post-traumatic stress disorder.³³⁶ In the process, FDA conducted “reviews of studies investigating the safety and effectiveness of marijuana, relevant professional societies’ position statements, data from state medical marijuana programs and U.S. national surveys, and the labeling of FDA-approved products relevant to the analysis.”³³⁷

FDA explained that for purposes of Part 2, certain “factors” supported “a positive finding,” i.e., that some credible scientific support exists for the medical use of marijuana in question. Such positive factors include:

1. favorable clinical studies of the medical use of marijuana, although not necessarily adequate and well-controlled clinical studies that would support approval of a new drug application (“NDA”), having been published in peer-reviewed journals and/or
2. qualified expert organizations (e.g., academic or professional societies, government agencies) having opined in favor of the medical use or provided guidance to HCPs on the medical use.³³⁸

Other factors “weigh against a finding that Part 2 of the CAMU test is met,” including:

³³³ *Id.*

³³⁴ Ctr. for Drug Evaluation & Rsch., FDA, Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act at 90 (Aug. 28, 2023) (“HHS Part 2 Analysis Memo”).

³³⁵ *Id.* at 3–4.

³³⁶ *Id.* at 4.

³³⁷ *Id.*

³³⁸ *Id.* at 11.

1. where data or information indicate that the medical use of the substance is associated with unacceptably high safety risks for the likely patient population, e.g., due to toxicity concerns;
2. clinical studies with negative efficacy findings for the medical use of marijuana having been published in peer reviewed journals; and/or
3. qualified expert organizations (e.g., academic or professional societies, government agencies) having recommended against the medical use of marijuana (based on the available data at the time of their position statement).³³⁹

After gathering and reviewing a broad swath of data and several studies, expert opinions, and the “position statements of professional organizations relevant to the indications discussed,” FDA concluded that “the totality of the available data” supports a finding “that, for purposes of the drug scheduling criteria in 21 U.S.C. 812(b), marijuana has a currently accepted medical use in the United States for: anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced); and pain.”³⁴⁰

FDA emphasized that while “the analysis and conclusions on the available data are not meant to imply that safety and effectiveness have been established for marijuana that would support FDA approval of a marijuana drug product for a particular indication,”³⁴¹ the totality of the evidence does “provide some level of support for the way marijuana is being used in clinical practice.”³⁴² In other words, the fact that FDA has concluded that cannabis has a CAMU for purposes of § 812(b)(1)(B) does *not* mean that FDA has approved cannabis as safe and effective for marketing as a drug in interstate commerce under the FDCA.

HHS recognized that its analysis and conclusion regarding marijuana’s CAMU differed from its and DEA’s approach to the CAMU issue in past marijuana rescheduling actions. In the past, DEA had concluded that a substance has a CAMU under the CSA only if it satisfied one of two tests. First, DEA had determined that a substance has a CAMU if FDA has approved the substance for interstate marketing under the FDCA, either through the NDA process or by meeting the criteria to be recognized as a “Generally Recognized As Safe and Effective” drug.³⁴³ Second, DEA had determined that a substance has a CAMU if it meets a five-part test that DEA established in 1992 based on the “core FDCA standards for acceptance of drugs for medical use”:

³³⁹ *Id.*

³⁴⁰ *Id.* at 7.

³⁴¹ *Id.*

³⁴² *Id.*

³⁴³ 57 Fed. Reg.10,499, 10,503 (March 26, 1992).

1. There must be adequate safety studies;
2. The drug's chemistry must be known and reproducible;
3. There must be adequate and well-controlled studies proving efficacy;
4. The drug must be accepted by qualified experts; and
5. The scientific evidence must be widely available.³⁴⁴

HHS acknowledged that it had departed from that approach in its most recent recommendation and evaluation of marijuana and explained its reason for the change.³⁴⁵ HHS informed DEA of its view that DEA's previous approach to determining whether a drug has a CAMU does not adequately account for certain indicia of medical use that, where present, are relevant to determining whether a substance has a CAMU for purposes of scheduling under the CSA.³⁴⁶ Specifically, HHS observed that DEA's tests left no room for an evaluation of (1) whether there is widespread medical use of a drug under the supervision of licensed health care practitioners under state-authorized programs and, (2) if so, whether there is credible scientific evidence supporting such medical use.³⁴⁷ HHS therefore developed an alternative test composed of those two inquiries as a third, independently sufficient approach for determining whether a substance has a CAMU under the CSA. HHS applied this two-part test to marijuana and recommended a finding that marijuana has a CAMU under the CSA.³⁴⁸

DEA questioned the legitimacy of HHS's two-part test and the appropriateness of its finding that marijuana has a CAMU.³⁴⁹ To resolve this dispute between DEA and HHS, the Attorney General referred several questions to OLC for authoritative resolution.³⁵⁰ Specifically, the Attorney General requested that OLC advise on whether HHS's test, if satisfied, established a CAMU "even if the drug has not been approved by FDA and even if the drug does not satisfy DEA's five-part test."³⁵¹ OLC determined that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, because it "ignor[es] widespread clinical experience with a

³⁴⁴ *Id.* at 10,503-06; *see also All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

³⁴⁵ NPRM, 89 Fed. Reg. at 44,617 ("In its most recent evaluation, HHS informed DEA of its view that DEA's previous approach to determining whether a drug has a CAMU does not adequately account for certain indicia of medical use that, where present, are relevant to determining whether a substance has a CAMU for purposes of scheduling under the CSA.").

³⁴⁶ *Id.*

³⁴⁷ *Id.*

³⁴⁸ *Id.* (citing HHS Basis for Rec. at 24-28).

³⁴⁹ *See* 48 Op. O.L.C. ___, *supra* note 8, at 19, 24 (noting DEA's disagreement with HHS on various issues and citing briefing from DEA that OLC received on those issues as part of its resolution of the questions presented).

³⁵⁰ NPRM, 89 Fed. Reg. at 44,617.

³⁵¹ *Id.* (citing 48 Op. O.L.C. ___, *supra* note 8, at 3).

drug that is sanctioned by state medical licensing regulators.”³⁵² OLC further opined that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU.³⁵³ And OLC concluded that, while HHS’s CAMU recommendation is not binding on DEA, the medical and scientific determinations that underlie its recommendation are binding until the initiation of formal rulemaking proceedings, and that DEA must accord those determinations “significant deference” throughout the rulemaking process.³⁵⁴

The Attorney General considered HHS’s recommendations and conclusions and accorded HHS’s scientific and medical determinations binding weight for purposes of assessing the appropriateness of initiating the formal rulemaking process.³⁵⁵ Applying HHS’s two-part test, and in light of OLC’s legal opinion that the HHS’s test is sufficient under the CSA, the Attorney General concurred with HHS’s conclusion that marijuana has a CAMU.³⁵⁶

We cannot improve on the points OLC made regarding the deficiencies associated with DEA’s five-part test for CAMU and the appropriateness of HHS’s two-part standard. We therefore register our support of that analysis and limit ourselves to a few additional points regarding CAMU.

First, while OLC refers to HHS’s two-part CAMU test as a “new” standard,³⁵⁷ HHS itself described it more accurately as an “update” to its existing approach.³⁵⁸ That is because FDA has long-recognized the potential relevance of state-regulated use of medical marijuana to the CAMU analysis. Addressing a previous marijuana rescheduling proceeding in 1982, for example, FDA emphasized that a drug could “obtain[] ‘accepted medical use’” for purposes of § 812(b)(1)(B) “by virtue of totally intrastate production and use.”³⁵⁹

Driving FDA’s deference to the practice of medicine at the state level both then and now is a core appreciation for the states’ traditional authority in that area. As OLC explained, the CSA “presume[s] and relies upon a functioning medical profession regulated under the States’ police powers.”³⁶⁰ The CSA therefore prohibits the federal government from making “anterior judgment[s]” about what constitutes accepted medicine or medical treatment, and “manifests no intent to regulate the practice of

³⁵² 48 Op. O.L.C. ___, *supra* note 8, at 13–14; *see also id.* at 12.

³⁵³ *Id.* at 4, 16–20.

³⁵⁴ *Id.* at 4, 20–26.

³⁵⁵ *See* NPRM, 89 Fed. Reg. at 80 (citing 48 Op. O.L.C. ___, *supra* note 8, at 24).

³⁵⁶ *See* NPRM, 89 Fed. Reg. at 44,619.

³⁵⁷ 48 Op. O.L.C. ___, *supra* note 8, at 3.

³⁵⁸ HHS Part 1 Analysis Memo at 1.

³⁵⁹ 47 Fed. Reg. 28,141, 28,150–51 (June 29, 1982).

³⁶⁰ *See* 48 Op. O.L.C. ___, *supra* note 8, at 13 (quoting *Gonzales*, 546 U.S. at 270).

medicine generally.”³⁶¹ DEA itself has acknowledged that it “does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies . . . collectively regulate the practice of medicine. In contrast, the scope of the CSA (and role of DEA) is much narrower.”³⁶²

HHS’s two-part standard is therefore nothing new but instead merely a more fleshed-out version of a long-settled principle. HHS did, to be sure, add more detail to the standard that FDA referred to in 1982, but there is nothing extraordinary about an agency stating a standard at only a general level and then explaining it more fully once confronted with a real-world situation to which it applies. That is what happened here. FDA recognized the centrality of intrastate production and use to CAMU decades ago. At that time, however, no substance had the sort of widespread state-regulated medical use that marijuana does today. For that reason, FDA had no occasion to flesh the standard out at that time. Marijuana today, with its widespread medical use under various state laws, presented the first compelling real-world example of the general principle FDA alluded to in 1982 and thus the first opportunity the agency had to flesh out the general standard further. Its decision to do so demonstrates consistent commitment to an interpretation of the CSA that it announced far closer in time to the statute’s enactment—precisely the sort of interpretation that courts afford “great respect.”³⁶³

Second, to the extent HHS’s application of the two-part test to assess marijuana’s CAMU marked a departure from the agency’s past practice, it took that step in a manner entirely consistent with bedrock principles of administrative law. Agencies are, after all, free to change their minds on such issues so long as they (1) acknowledge the change and (2) provide a reasoned explanation for the new approach.³⁶⁴ The Proposed Rule explains that HHS informed DEA of its view that DEA’s previous approach to determining whether a drug has a CAMU does not adequately account for certain indicia of medical use that, where present, are relevant to determining whether a substance has a CAMU for purposes of scheduling under the CSA.³⁶⁵ Specifically, HHS observed that DEA’s tests left no room for an evaluation of (1) whether there is widespread medical use of a drug under the supervision of licensed health care practitioners under state-authorized programs and, (2) if so,

³⁶¹ *Gonzales*, 546 U.S. at 272, 270.

³⁶² 71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006). *See also* 57 Fed. Reg. at 10,505 (DEA acknowledging that the CSA “does not authorize . . . the DEA Administrator[] to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word ‘accepted’ out of the statutory standard”).

³⁶³ *See, e.g., Loper Bright Enters. v. Raimondo*, No. 22-451, slip. op. at 8 (U.S. June 28, 2024).

³⁶⁴ *See, e.g., Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016) (“When an agency changes its existing position, it . . . must at least display awareness that it is changing position and show that there are good reasons for the new policy.” (quotation marks and citation omitted)).

³⁶⁵ NPRM, 89 Fed. Reg. at 44,617.

whether there is credible scientific evidence supporting such medical use.³⁶⁶ HHS therefore developed an alternative test composed of those two inquiries as a third, independently sufficient approach for determining whether a substance has a CAMU under the CSA. HHS applied this two-part test to marijuana and recommended a finding that marijuana has a CAMU under the CSA.³⁶⁷ This explanation more than satisfies HHS's obligation under the Administrative Procedure Act ("APA") for announcing a change in position.

Relatedly, to the extent that DOJ's acceptance of HHS's two-part test and its CAMU recommendation for purposes of initiating proceedings marks a change in DOJ's approach to the issue, it, too, has complied with the APA's strictures. As the Proposed Rule explains, recognizing that HHS's approach represented the first time the agency had applied the two-part test to assess CAMU under the CSA, the Attorney General referred the validity of the standard itself and HHS's application of it to marijuana to OLC for review.³⁶⁸ After hearing from the agencies involved and considering the issue, OLC confirmed that (1) HHS's two-part test reflects a valid interpretation of the statute and (2) its resolution of scientific and medical issues embedded in the CAMU analysis is binding on DEA at least until the initiation of formal rulemaking proceedings under 21 U.S.C. § 811.³⁶⁹ After reviewing HHS's recommendation and OLC's analysis, the Attorney General concluded that they were correct to conclude that HHS's two-part test should govern the CAMU analysis for marijuana.³⁷⁰ The Attorney General then took the unusual step of publishing both HHS's analysis and OLC's opinion addressing this issue (and others) as part of the rulemaking docket available for public review.³⁷¹

Third, OLC's mandate that DEA must afford HHS's scientific and medical determinations "significant deference" throughout the rulemaking process imposes an exacting standard on DEA for departing from HHS's findings.³⁷² While OLC did not explain in any detail what "significant deference" means in this context, we believe that it precludes DEA from ignoring HHS's otherwise binding scientific and medical determinations in the absence of exceedingly compelling evidence of clear error. DEA's mere disagreement with HHS—no matter how strongly felt—is not sufficient.

³⁶⁶ *Id.*

³⁶⁷ *Id.* (citing HHS Basis for Rec. at 24–28).

³⁶⁸ *Id.*

³⁶⁹ See 48 Op. O.L.C. ___, *supra* note 8, at 3 n.3 (explaining that "[t]o aid [its] analysis," OLC "solicited and received written views from HHS and DEA on all three questions and from the State Department on the third question"); *id.* at 23-26 (analyzing the CAMU standard issue and agreeing with HHS's view).

³⁷⁰ NPRM, 89 Fed. Reg. at 44,619.

³⁷¹ *Id.* at 44,599 n.1.

³⁷² 48 Op. O.L.C. ___, *supra* note 8, at 23.

Federal administrative agencies often must afford “significant deference” to one another, particularly when exercising delegated authority under a so-called “dual-delegation” statute such as the CSA.³⁷³ And even without a “significant deference” mandate like the one DEA operates under here vis-à-vis HHS, agencies are generally obligated to defer to one another’s expertise.³⁷⁴ *A fortiori*, here, where DEA is compelled by plain statutory text to yield to HHS on these particular issues in this particular context, it should do so with only the very rarest of exceptions. Even Article III courts, which operate under a constitutional mandate to exercise their independent judgment in resolving cases and controversies, afford significant deference to the scientific and medical determinations of an expert agency, particularly where, as here, the agency acts under an express statutory delegation entrusting the particular question to that agency for resolution.³⁷⁵

HHS’s findings need not be “perfect” or the “best,” and “some imprecision” is permissible.³⁷⁶ To overcome such significant deference, the agency entitled to that deference must have made a “clear error of judgment.” It is not enough that the deferring agency finds opposing viewpoints more persuasive.³⁷⁷ As OLC put it, “DEA may not simply cast aside HHS’s scientific and medical recommendations once it initiates formal rulemaking proceedings,” and “section 811(b) suggests that Congress intended HHS’s scientific and medical views to at least be a very significant input in the scheduling process.”³⁷⁸

In sum, OLC’s mandate that DEA must afford “significant deference” to HHS’s medical and scientific findings requires DEA to yield to those findings in every instance unless substantial evidence submitted during the rulemaking process not

³⁷³ See, e.g., FTC, ENFORCEMENT POLICY STATEMENT ON FOOD ADVERTISING (May 13, 1994), <https://www.ftc.gov/legal-library/browse/enforcement-policy-statement-food-advertising#30>; see also *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986).

³⁷⁴ See, e.g., *City of Boston Delegation v. FERC*, 897 F.3d 241, 255 (D.C. Cir. 2018) (“Agencies can be expected to ‘respect [the] views of such other agencies as to those problems’ for which those ‘other agencies are more directly responsible and more competent.’”) (quoting *City of Pittsburgh v. Fed. Power Comm’n*, 237 F.2d 741, 754 (D.C. Cir. 1956)).

³⁷⁵ See *Loper Bright Enters.*, No. 22-451, slip op. at 17-18; *Murray Energy Corp. v. EPA*, 936 F.3d 597, 616 (D.C. Cir. 2019) (per curiam) (“EPA reasonably explained why it thought those studies were unreliable, and its ‘evaluation of scientific data within its technical expertise’ is entitled significant deference.”); *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (“When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.”).

³⁷⁶ See *Bradley Mining Co. v. EPA*, 972 F.2d 1356, 1359 (D.C. Cir. 1992).

³⁷⁷ *Marsh v. O. Nat. Res. Council*, 490 U.S. 360, 378 (1989) (unanimous) (“When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.”); *Tongass Conservation Soc’y, Greenpeace v. U.S. Forest Serv.*, Case No. 010-cv-000006, 2010 WL 11534489, at *7 (D. Alaska Mar. 8, 2010) (“Given its extensive analysis and the fact that this is a highly scientific determination in which the Court must give the agency significant deference, the Court cannot conclude that the Forest Service made a ‘clear error of judgment’ or that its decision must be reversed.”), *aff’d sub nom. Tongass Conservation Soc’y v. U.S. Forest Serv.*, 385 F. App’x 708 (9th Cir. 2010).

³⁷⁸ 48 Op. O.L.C. ___, *supra* note 8, at 25.

only contradicts HHS's determinations but demonstrates that HHS clearly erred. A standard any less exacting would upend Congress's careful and intentional distribution of authority between DEA and HHS for purposes of rescheduling decisions under § 811 of the CSA.³⁷⁹

International Treaty Issues Do Not Pose an Obstacle to Scheduling Reform

We agree with OLC that U.S. obligations under the Single Convention on Narcotic Drugs do not bar DEA and/or DOJ from transferring marijuana to schedule III of the CSA.³⁸⁰ While we understand that OLC's view on such legal question is binding on DEA, to the extent that DOJ and/or the Attorney General disagrees with OLC's analysis on this point, we reserve our right to challenge the constitutionality of 21 U.S.C. § 811(d)(1) under the private non-delegation doctrine.³⁸¹

OLC concluded that DEA could transfer marijuana to schedule III and ensure treaty compliance through separate regulatory controls as necessary to close the “modest gap” between the Single Convention's mandates and the controls associated with schedule III classification itself.³⁸² We do not believe additional regulatory controls are necessary because Congress itself has signaled that treaty compliance is not “appropriate” in the marijuana context by removing hemp, including synthetic IHDCs, from the ambit of the CSA altogether through the 2018 Farm Bill.

Months before the 2018 Farm Bill's passage, DEA insisted that the cannabis-derived drug Epidiolex, which qualified as marijuana under the CSA definition in place at that time, could not be removed from the CSA entirely because doing so would make it impossible for the United States to carry out its obligations under the Single Convention.³⁸³ Congress's decision to override that DEA decision months later by removing Epidiolex from the CSA's schedules entirely is powerful evidence that when it comes to cannabis at least, Congress does not believe that U.S. treaty obligations make placement on any of the CSA's schedules “appropriate.”³⁸⁴

In case DEA, DOJ, and/or a court disagree, the only additional regulatory controls that could possibly be necessary would be those that DEA applied to Epidiolex when placing it in schedule V. Again, at that time, Epidiolex qualified as marijuana under the CSA, and DEA recognized that it also qualified as cannabis

³⁷⁹ Now that HHS has affirmed that marijuana has a CAMU, DEA must amend or remove its regulations defining “medicinal cannabis” and “cannabis preparation” in ways that contradict that determination. *See* 21 C.F.R. § 1318.02(b)-(c).

³⁸⁰ *See* 48 Op. O.L.C. ___, *supra* note 8, at 1, 26–36.

³⁸¹ *See* Shane Pennington & Matthew C. Zorn, *The Controlled Substances Act: An International Private Delegation That Goes Too Far*, 100 WASH. UNIV. L. REV. ONLINE 29, 50 (2023).

³⁸² 48 Op. O.L.C. ___, *supra* note 8, at 33.

³⁸³ *See* 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018).

³⁸⁴ 21 U.S.C. § 811(d)(1) (requiring the Attorney General, and thus DEA, to place substances subject to control under the Single Convention in the CSA schedule he “deems most appropriate” to carry out U.S. treaty obligations).

under the Single Convention. Accordingly, DEA understood itself to be obligated to impose separate regulatory controls as necessary to close the gap between the Single Convention's cannabis-related requirements and the obligations that the CSA already imposes on schedule V substances. The only two additional controls that DEA found necessary to impose were certain quota requirements and import/export requirements. Because schedule V is *less* restrictive than schedule III, it would make no sense to conclude that stricter additional controls are necessary for schedule III marijuana than were necessary to align schedule V Epidiolex with U.S. treaty obligations.

If DEA and/or DOJ does conclude that additional regulatory controls beyond those associated with schedule III placement are necessary here, the APA and core administrative-law principles demand that it promulgate those additional controls through a transparent rulemaking process that includes at least the level of notice and public participation associated with informal rulemaking under the APA's traditional notice-and-comment process.³⁸⁵

Conclusion

For the foregoing reasons, ATACH and its members agree with our leading health agencies and the Attorney General of the United States, that marijuana should be reclassified to schedule III. Marijuana has an established "currently accepted medical use in treatment in the United States" and a lower abuse potential than any controlled substances in schedules I and II. The decision to reschedule marijuana to schedule III thus comports with the science, the law, and 21st-century realities.³⁸⁶

The United States has both an opioid and alcohol epidemic on its hands. And consumer demand for marijuana will not wane. Our choice is simple: expend precious public health and law enforcement resources on a largely innocuous plant that has never caused overdose or death, or refocus our efforts and resources where they appropriately belong. Common sense dictates that the federal government should focus on the drugs that are killing people and wreaking havoc on our nation. And they should leave marijuana regulation to the 38 state regulators who are already protecting public health and safety.

State regulators are consistently making sure that marijuana products are marketed and sold only to adults, are marketed and sold only intrastate, and abide by age verification, lab testing, warning label, and packaging and labeling standards. These state regulators have proven that they are up to the task. It's time that the

³⁸⁵ As the NPRM explains, the Attorney General retains authority to make final scheduling decisions in the first instance despite having delegated his authority in that regard to the DEA Administrator by regulation. *See* 89 Fed. Reg. at 44,601 (citing 28 U.S.C. §§ 509, 510). To the extent DEA fails to execute its delegated authority with respect to these proceedings, the Attorney General should not hesitate to carry out Congress's commands himself in the first instance.

³⁸⁶ While we believe that marijuana should be descheduled, we understand that this administrative process only allows for rescheduling, and we support rescheduling marijuana to schedule III.

federal government permit the states to exercise their traditional police powers to protect public health. Leaving marijuana in schedule I—or placing it in schedule II—would serve only to embolden those who sell dangerous illicit-market products and unregulated synthetic IHDCs. Public health and safety demand a schedule III placement for marijuana. So does the science.

Michael Bronstein, President³⁸⁷

American Trade Association for Cannabis and Hemp (ATACH)

Andrew J. Kline
Perkins Coie LLP

Shane Pennington
Porter, Wright, Morris, & Arthur LLP

³⁸⁷ The Coalition for Cannabis Scheduling Reform, a committee of ATACH, thanks our community of significant contributors which can be found at <https://schedulingreform.org/coalition-comment>.

Exhibit 1



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June 17, 2024

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Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrisette Drive
Springfield, VA 2215

Re: Notice of Appearance

Dear Sir:

Please take notice that American Trade Association for Cannabis and Hemp (“ATACH”) requests to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the “Proposed Rule”), if DEA grants any other interested person’s petition for a hearing.

(A) ATACH has standing to participate in a hearing if one occurs. ATACH is an “interested person” and falls within the CSA’s zone of interests. Further, ATACH and its members will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized. ATACH’s status as an “interested person” is further detailed in the enclosed submission.

(B) Among other things, ATACH has unique expertise and would provide invaluable insights into: (i) medical research involving marijuana, particularly as it relates to veterans’ access; (ii) effects on members who are minority-owned and small businesses and whose communities have been impacted by the war on drugs; (iii) the impact of new marijuana-specific DEA controls on ATACH’s members; (iv) abuse potential and public health risks of marijuana and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. Further detail about the objections or issues on which ATACH desires to be heard is provided in the enclosed submission.

(C) ATACH represents a coalition of active participants in and around the state-legal cannabis industry that are directly and adversely affected by the Proposed Rule. ATACH is thus uniquely situated to assist DEA’s administrative decision making if DEA desires a hearing. ATACH and its members have extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated marijuana marketplace. DEA is actively seeking comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. ATACH is particularly well-suited to provide this insight, as it represents a broad coalition of interests, including (but not limited to) distributors, seed-to-sale technology providers, economic consultants, ingredient and garden care suppliers, financial service providers serving the cannabis industry, non-profit researchers, and veterans groups, among

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
June 17, 2024
Page 2

other voices. ATACH's positions with regard to the particular objections or issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to:

Abdul Kallon
1201 Third Ave., Ste. 4900
Seattle, WA 98101

Respectfully yours,

/s/ Abdul Kallon
Abdul Kallon

AK:tjt

The logo for PERKINScoie, with "PERKINS" in red and "coie" in black.The logo for porterwright, with "porter" in red and "wright" in black.

June 17, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrisette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: DEA Federal Register
Representative/DPW
8701 Morrisette Drive
Springfield, Virginia 22152

Re: Request to Participate in a Hearing & Notice of Appearance

Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Administrator Milgram:

Pursuant to 21 C.F.R. § 1308.44(c) and § 1316.48, the American Trade Association for Cannabis and Hemp (“ATACH”) submits, as an “interested person,” this Request to Participate in a Hearing and Notice of Appearance, if DEA grants any other interested person’s petition for a hearing.¹ Should DEA schedule a hearing before an Administrative Law Judge (“ALJ”), ATACH will submit declarations supporting expert and fact witness testimony for that hearing in due course.

ATACH is an Internal Revenue Service-recognized 501(c)(6) entity. ATACH’s member companies and organizations include businesses, professional firms, and state trade associations involved in or serving the marijuana and hemp industries. ATACH and its member companies and organizations are interested persons within the zone of interest and will be adversely affected or aggrieved by this proposed rule, entitled *Schedules of Controlled Substances: Rescheduling of Marijuana*, if finalized. See 89 Fed. Reg. 44,597 (May 21, 2024) (the “Proposed Rule”).

ATACH has standing to participate in a hearing. Among other things, ATACH has unique expertise and provides invaluable insights into: (i) medical research involving marijuana, particularly as it relates to veterans’ access; (ii) effects on members who are minority-owned and small businesses and whose communities have been impacted by the War on Drugs; (iii) the impact of new marijuana-specific DEA controls on ATACH’s members; (iv) abuse potential and public health risks of marijuana, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. ATACH is prepared to present expert testimony on these issues

¹ If another interested person’s petition is granted, but the issues raised, in whole or in part, therein are not covered by the instant petition, we request an opportunity to re-submit our request to participate. ATACH further reserves its right to supplement its petition.

Administrator Milgram
June 17, 2024

Page 2

as well as, *inter alia*, marijuana's currently accepted medical use in treatment in the United States, relevant international treaty obligations, and the placement of marijuana on the Controlled Substances Act's ("CSA") schedules. ATACH's testimony would materially assist a DEA ALJ in preparing a sound and well-supported administrative decision.

A.

On May 21, 2024, DOJ issued a Notice of Proposed Rulemaking, *Schedules of Controlled Substances: Rescheduling of Marijuana*. Proposed Rule at 44,597. The Proposed Rule noted that DEA may hold a hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III on the list of controlled substances." *Id.* at 44,599 (cleaned up). Concurrently, the agency is considering "marijuana-specific controls that would be necessary to comply with relevant treaty obligations in the event that, after the hearing, a final order reschedules marijuana." *Id.* DEA will presumably consider any such updated controls during this rulemaking.

This request to participate in a hearing (if one is scheduled) is timely filed. As noted in the Proposed Rule, interested persons must comply with a postmark or receipt deadline of June 20, 2024, to file a request for hearing, waiver of opportunity to be heard, or request to participate in a hearing.

This request to participate serves to inform DEA that ATACH is an interested person and intends to participate in DEA's rulemaking process to the fullest extent possible, including at any administrative hearing DEA decides to grant. ATACH is separately submitting a public comment on the Proposed Rule on behalf of its members, the cannabis industry and its ancillary businesses, researchers, social equity license holders, medical providers, and medical patients, including veterans.

B.

ATACH is a prominent national trade organization promoting the legal and regulatory framework for the marijuana and hemp industries in the United States in partnership with its member companies. Founded in 2014 in response to the evolving legal landscape of marijuana and hemp, ATACH works to influence public policy, promote industry growth, and enhance the commercial environment for both industries. Based in Washington, D.C., ATACH collaborates closely with state and federal lawmakers, regulatory agencies, researchers, standards organizations, accreditation bodies, and industry stakeholders to foster a viable, safe, and regulated marijuana and hemp market with particular attention on public health and safety and consumer protection.

ATACH is particularly focused on areas such as product safety, industry standards, legislative advocacy, education, and research within the marijuana and hemp sectors. It provides its members

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with critical information on regulatory changes, market trends, and legal challenges. ATACH has a vested interest in seeing that its member companies succeed and that they are economically viable, and in ensuring that Americans' use of marijuana and hemp products is safe and medicinally beneficial.

ATACH has spent extensive time, money, and other resources to advocate for a regulated, responsible marijuana marketplace. ATACH's interests and resource expenditures would be at risk if ATACH were not permitted to participate in the formal rulemaking process to the fullest extent permitted by law.

The Proposed Rule directly affects ATACH and its members. Specifically, ATACH and its members may be subject to new DEA registration requirements as well as new DEA controls, such as potential new controls regarding the manufacturing and sale of marijuana. If DEA eschews the Proposed Rule and decides that marijuana should remain on schedules I or II, that decision would also adversely affect ATACH and its members with significant tax consequences, as well as by creating difficulty in testing state-regulated products, conducting medical research, assisting veterans, and supporting minority-owned and other small businesses.

C.

The Proposed Rule represents a sea change in how the federal government proposes to regulate the nation's marijuana market. As DEA is aware, marijuana is currently categorized as a schedule I substance, making it subject to the most stringent controls. Schedule I substances, according to DEA's classification, have no currently accepted medical use and a high potential for abuse. Some examples of schedule I drugs are heroin, LSD, ecstasy, and peyote.²

ATACH maintains that marijuana does not belong in schedules I or II, particularly given its accepted medical utility and demonstrated low potential for abuse. As detailed in the Proposed Rule, the Department of Health and Human Services ("HHS") conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III. 89 Fed. Reg. at 44,600. Specifically, HHS concluded that marijuana has a potential for abuse less than the other substances in schedules I and II; that marijuana has a currently accepted medical use in treatment in the United States; and that the abuse of marijuana may lead to moderate or low physical dependence or psychological dependence. *Id.* In addition, 38 states, the District of Columbia, and four territories have legalized the use of medical marijuana, allowing the use of the substance to treat certain health conditions, including chronic pain. *Id.* In contrast, schedule II substances are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs

² DEA, *Drug Scheduling*, <https://www.dea.gov/drug-information/drug-scheduling>.

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are also considered dangerous. Some examples of schedule II drugs are cocaine, methamphetamine, methadone, oxycodone, and fentanyl.³

The public health risks of marijuana are not similar to the “comparator substances controlled” under schedules I and II reviewed in the Proposed Rule. ATACH’s participation in the administrative hearing process would demonstrate that marijuana compares favorably to the public health risks of substances in schedules I and II like heroin (schedule I), cocaine (schedule II), or fentanyl (schedule II). *See* Proposed Rule at 44,614 (discussing HHS’ recommendation on this point); *see also id.* at 44,618 (noting that heroin, cocaine, and fentanyl were considered “comparator substances controlled” under schedules I and II). According to data from the Centers for Disease Control and Prevention (“CDC”), heroin, cocaine, and fentanyl are responsible for tens of thousands of fatalities in the United States annually.⁴ In fact, DEA has launched a public awareness campaign that even “One Pill” of fentanyl “Can Kill,” noting that two milligrams of fentanyl (an amount smaller than a pencil tip) can be deadly.⁵ Given its deadly nature, the risk profile of fentanyl—a schedule II substance—dwarfs that of marijuana. DEA itself recognizes that zero deaths have been associated with marijuana overdose.⁶ ATACH has significant interest in making certain that any administrative hearing includes the best and most accurate current scientific knowledge.

While the Proposed Rule would reschedule marijuana to schedule III, certain crucial consequences of this momentous decision remain unanswered. ATACH and its members are well positioned to present evidence addressing these unanswered questions. ATACH is a trade association with membership that includes many of the leading participants in the state-legal, regulated marijuana marketplace. Some of ATACH’s members are “plant touching” companies, some provide ancillary services to the state-legal industry, and some are non-profit research and advocacy organizations. The Proposed Rule will, once finalized, directly affect ATACH and its constituent members. Among other things, “if marijuana is transferred into schedule III, DEA will continue to have authority to maintain its existing regulatory scheme . . . governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marijuana.” *Id.* at 44,620. *See also id.* at 44,621 (“If marijuana is transferred to schedule III, the regulatory controls applicable to schedule III-controlled substances would apply, as appropriate.”). In other words, ATACH and its members may be subject to new DEA registration requirements regarding the manufacturing of marijuana or marijuana products, as well as any other regulatory controls applicable to schedule III substances. Accordingly, ATACH requests to participate in a hearing if DEA convenes one.

³ DEA, *Drug Scheduling*, <https://www.dea.gov/drug-information/drug-scheduling>.

⁴ CDC, *Provisional Drug Overdose Death Counts*, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁵ DEA, *One Pill Can Kill*, <https://www.dea.gov/onepill>.

⁶ DEA, *Marijuana/Cannabis: Drug Fact Sheet* at 3 (April 2020), https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf.

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D.

ATACH has standing to participate in a hearing if one occurs. ATACH is an “interested person” and falls within the CSA’s zone of interests. Further, ATACH and its members will be directly and “adversely affected” or “aggrieved” by the Proposed Rule if finalized.

1.

The Proposed Rule is a “scheduling action” issued under 21 U.S.C. § 811(a). *Id.* at 44,598; *id.* at 44,621. The Administrative Procedure Act (“APA”), the CSA, and DEA regulations set out the governing standards for this scheduling action and related rulemaking proceedings. *See id.* at 44,598–99.

Under the APA, 5 U.S.C. § 555(b), “an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding,” “[s]o far as the orderly conduct of public business permits.” DEA regulations accordingly provide that an “interested person” may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c).

DEA regulations, in turn, define “interested person” as “any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. § 811].” 21 C.F.R. § 1300.01(b).⁷ As the Proposed Rule was promulgated under 21 U.S.C. § 811(a), DEA’s definition of “interested person” may apply here. *See* Proposed Rule at 44,598; *id.* at 44,621. We note that DEA has not formally defined “adversely affected or aggrieved” for purposes of the definition of an “interested person.” *See In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022) at 2 (“ALJ Order”).⁸ In recent scheduling actions, however, DEA has argued that a person qualifies as an “interested person” only if they can demonstrate the equivalent of Article III standing to pursue litigation in federal court. *See* ALJ Order at 4. ALJs have correctly rejected that argument, however, concluding instead that it is sufficient that a person falls within the CSA’s “zone of interests.” *See id.* at 5–6. As the discussion that follows demonstrates, ATACH qualifies as an interested person under either standard.

2.

ATACH is an “interested person” for two primary reasons.

First, ATACH falls within the CSA’s “zone of interests.” In May 2022, a DEA ALJ concluded that the test for “adversely affected or aggrieved”—and consequently, “interested person”—was

⁷ Pursuant to 21 C.F.R. § 1300.01(b), “person” includes “any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.”

⁸ The ALJ Order is attached here as Exhibit A.

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satisfied when the person fell within the “zone of interests” to be regulated by the CSA. ALJ Order at 10. The Supreme Court of the United States has explained that the “zone of interests” test is “not meant to be especially demanding” given Congress’ intent to “make agency action presumptively reviewable.” *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (citation omitted).

A party falls “within the zone of interests,” the ALJ explained, “if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question.” ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). With regard to the CSA, the Supreme Court has noted that the statute was enacted with “the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Oregon*, 546 U.S. 243, 250 (2005).

ATACH falls within the CSA’s zone of interests. To start, ATACH and its members are regulated by the Proposed Rule and the CSA. ATACH and its members are actively involved in the state-legal marijuana industry. Each day, ATACH and its members work to support the state-regulated market for marijuana and marijuana products and actively fight against the perils of the illicit marketplace and unregulated hemp-derived intoxicants. And as we outline more below, ATACH and its members may see new marijuana-specific controls related to marijuana-related activities under the Proposed Rule. Proposed Rule at 44,620–21.

Second, ATACH and its members would be adversely affected or aggrieved by the Proposed Rule, if finalized. ATACH and its members are prepared to present evidence on these facts at a hearing if one is convened:

- ***Veterans and Medical Research:*** Opportunities for research in schedule III are more limited than if marijuana were to be descheduled, which would have a notable impact on ATACH member veterans and their ability to access plant-based medicine as an alternative to opioids. Some of ATACH’s members, including the non-profit Hemp for Victory, actively advocate for research and access to medical cannabis for veterans. As a coalition with members like Hemp for Victory, ATACH is well positioned to represent the interests of veterans who are seeking alternatives to opioids and who would benefit from the loosening of research protocols. Hemp for Victory’s prior petition calling for rescheduling of marijuana to schedules III, IV, or V, and descheduling for these reasons is attached here as Exhibit B.

Hemp for Victory is already adversely affected and aggrieved by the Proposed Rule for another, independent reason, namely DEA’s failure to respond to its petition seeking to reschedule or deschedule marijuana, challenging the constitutionality of certain statutory provisions bearing on the scope and substance of the Proposed Rule, and requesting that its petition be joined with the ongoing administrative action to reconsider marijuana’s

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schedule I classification in the wake of the President’s October 6, 2022, directive. The APA requires DEA to provide a timely response to such petitions and requests. *See* 5 U.S.C. § 555(b) (requiring agencies to act within a reasonable time). Because Hemp for Victory’s petition bears directly on the matters and issues at play in this rulemaking, raises fundamental statutory and constitutional issues, and requests, among other relief, precisely the remedy that the Proposed Rule contemplates, DEA’s failure to acknowledge—much less resolve the petition and Hemp for Victory’s request for joinder adversely affects and aggrieves Hemp for Victory directly and concretely. It would therefore be especially improper to exclude Hemp for Victory from any administrative hearing related to the Proposed Rule.

- ***Small and Minority-Owned Businesses and the Minority Cannabis Business Association:*** The Minority Cannabis Business Association (“MCBA”)—an ATACH member—advocates for the success of small and minority-owned businesses in the marijuana industry. The opportunities for many MCBA-member businesses, while essential, are also currently limited compared to what they would be if marijuana were descheduled. Significantly, criminal penalties will not change in schedule III, so MCBA members who are invested in criminal justice reform will see no change in sentencing protocols. As a result, MCBA and its members fall within the zone of interests and will be aggrieved by the Proposed Rule, if finalized, because it would not deschedule marijuana.⁹ MCBA also has equities in the outcome of this rule because small businesses need the tax relief schedule III promises. They would therefore also be aggrieved by any final rule

⁹ Throughout HHS’ evaluation, investigators compared the safety profile and abuse potential of cannabis versus several other controlled substances, which they referred to as “comparator drugs.” *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (with enclosures) (Aug. 29, 2023) at PDF 8–9, <https://www.dropbox.com/scl/fi/pw3rfs9gm6lg80ij9tja6/2023-01171-Supplemental-Release-1.pdf?rlkey=v5atj0tcnfxhnszyzcwdcvvt&e=1&dl=0>. These comparator drugs not only included other schedule I substances like heroin, but also included substances classified in lower schedules, such as benzodiazepines (schedule IV) and alcohol—which is unscheduled. Notably, on several occasions throughout its report, HHS concluded that cannabis poses a lower public health risk than these latter two substances. For instance, HHS concluded, “[t]he most notable conclusion from an evaluation of various epidemiological databases related to the medical outcomes from abuse of selected drugs is that for all measures that were evaluated from 2015 to 2020, the rank order of the comparators in terms of greatest adverse consequence typically places alcohol, heroin, and/or cocaine in the first or immediately subsequent positions, with marijuana in a lower place in the ranking.” *Id.* at PDF 46. HHS later reaffirmed this conclusion, acknowledging: “The risks to the public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological data bases for ED visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths. . . . These evaluations demonstrate that there is consistency across databases, across substances, and over time and that although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator drugs.” *Id.* at PDF 9. While HHS ultimately recommended transferring cannabis from schedule I to schedule III, its favorable safety profile as compared to substances that are currently categorized in lower classifications—or, as in the case of alcohol, not scheduled at all—provide an argument in favor of descheduling cannabis entirely.

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placing marijuana in schedule II or maintaining its schedule I placement. MCBA represents minority-owned and allied cannabis businesses, aspiring entrepreneurs, and supporters who share a vision of an equitable, just, and responsible cannabis industry. MCBA advocates for “social equity” in the cannabis industry that, among other things, empowers and supports the communities most affected by the War on Drugs. The Proposed Rule is silent as to equity considerations and how the Proposed Rule’s prospective controls may affect diverse communities. It is important for a hearing to address those issues given (i) the social equity issues inherent in the nation’s cannabis policies and (ii) the mandate of Executive Order 13,985 that “each agency must assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.” Executive Order 13,985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (Jan. 20, 2021). MCBA—as a member entity of ATACH—can provide testimony and evidence that can assist DEA in understanding the ramifications of its Proposed Rule on communities of color. Therefore, ATACH member MCBA has standing to participate in any ALJ hearing should one be granted. Under settled associational standing principles, MCBA’s standing further reinforces ATACH’s standing to participate as well. *See, e.g., Students for Fair Admissions, Inc. v. Pres. & Fellows of Harvard Coll.*, 600 U.S. 181, 199 (2023) (“In cases . . . where the plaintiff is an organization, the standing requirements of Article III can be satisfied in two ways. Either the organization can claim that it suffered an injury in its own right or, alternatively, it can assert ‘standing solely as the representative of its members.’”) (quoting *Warth v. Seldin*, 422 U. S. 490, 511 (1975)).

ATACH satisfies both of the standing tests reviewed in *Students for Fair Admissions*. Under the first test, an organization may demonstrate standing by showing that it is injured in its own right. 600 U.S. at 199. As described throughout this request, ATACH has suffered a concrete injury itself as a result of the Proposed Rule. Among other things, ATACH spends time, money, and other resources to advocate for a regulated, responsible marijuana marketplace, and the Proposed Rule imperils these expenditures.

Under the second test, associational standing is demonstrated when an organization can show “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Id.* (quoting *Hunt v. Washington State Apple Advertising Comm’n*, 432 U.S. 333, 343 (1977)). ATACH meets each of these three elements. As discussed above, Hemp for Victory and MCBA—among other ATACH member entities—have standing to participate, which, in turn, confers standing upon ATACH. The interests ATACH seeks to protect are germane to the organization’s purpose: to foster a viable, safe, and regulated marijuana and hemp market with particular attention on public health and safety and

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consumer protection. ATACH can serve as a representative of its members in this proceeding, and the participation of individual member entities is not required.

- ***The Impact of New Marijuana-Specific Controls on ATACH and its Members:*** Concurrent with this rulemaking, the agency is considering marijuana-specific controls associated with international treaty obligations. Proposed Rule at 44,599. The Office of Legal Counsel (“OLC”) concluded that “additional controls pursuant to the CSA’s regulatory authorities” may be necessary. OLC, *Questions Related to the Potential Rescheduling of Marijuana*, at 4 (Apr. 11, 2024).¹⁰ New DEA controls would adversely impact how ATACH’s members operate and would impose new costs. For instance, testing laboratories are not currently required to hold a DEA license under the state-regulated programs. Requiring them to register with DEA would be costly and arduous. DEA rules could also require that the agency play a role in the handling of final products, including burdensome paperwork, storage requirements, and methods of destruction. ATACH and its laboratory members may also be subject to new DEA registration requirements and controls applicable to schedule III substances. *See* Proposed Rule at 44,620–21. Compliance with these potential requirements could require increased staffing costs, costly modifications to laboratory facilities and contracting with DEA-licensed disposal firms. Requiring laboratories to become DEA licensed could also prevent them from accepting products from the state-licensed marijuana market as well as the hemp market, rendering their businesses obsolete. Thus, ATACH and its lab member companies are adversely impacted by the uncertainty surrounding the promulgation of new DEA controls or the enforcement of existing rules that currently remain unenforced. ATACH is prepared to produce affidavits from the Chief Scientific Officers of two of its member laboratories, ACT Labs and ProVerde Laboratories. These laboratories are not only within the zone of interest but are also aggrieved because of the uncertainties surrounding new or updated DEA controls.

Similarly, under the status quo, DEA does not enforce its regulatory requirements obligating cannabis labs to accept cannabis sample material only from other DEA-registered entities. This non-enforcement policy is essential to state-licensed labs like ACT Labs and ProVerde Laboratories, because the vast majority of the entities submitting samples to cannabis labs nationwide are not themselves registered with DEA. And because these entities have handled cannabis in violation of federal law, DEA’s current policies effectively bar them from becoming registered even if they wanted to. Were DEA to enforce these policies in a post-rescheduling world, companies like ACT Labs and ProVerde Laboratories would be regulated out of existence in short order. Under traditional association standing principles, their standing establishes ATACH’s standing

¹⁰ This OLC opinion is attached as Exhibit C.

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as well. *See Students for Fair Admissions, Inc.*, 600 U.S. at 198–201.

Another specific example involves ATACH members like PharmaCann, Inc., which serves the state-regulated *medical* marijuana market in particular. Despite the millions of patients and tens of thousands of licensed healthcare professionals using and recommending medical marijuana products in treatment across the country, the federal government had, until this administrative process, repeatedly insisted that marijuana had no currently accepted medical use in treatment in the United States. As a result, for federal law and U.S. treaty compliance purposes, the federal government had always insisted that the Single Convention’s regulating and reporting requirements with respect to the medical use of cannabis did not apply to the products being used in the state-regulated medical marijuana markets. The federal government’s recent acknowledgment in this rulemaking process that cannabis does, in fact, have medical utility undercuts the federal government’s longstanding rationale for treating these particular treaty requirements as inapplicable to state-regulated medical marijuana regimes. As such, ATACH members like PharmaCann who serve and operate within the state-regulated medical marijuana space now face the prospect of new and burdensome regulatory compliance obligations stemming from these long-dormant U.S. treaty obligations. The costs associated with bearing these looming regulatory burdens independently demonstrate the adverse effect the Proposed Rule would have on ATACH members like PharmaCann, if finalized.

- ***Abuse Potential, Public Health Risks, and the Illicit Market:*** The public health risks of marijuana are far less significant than fentanyl, cocaine, or other controlled substances in schedule II. ATACH is prepared to present expert testimony on marijuana’s abuse potential, currently accepted medical use in treatment in the United States, and the placement of marijuana on the CSA’s schedules. Dr. Malik Burnett, an addiction specialist, is prepared to testify about the abuse potential of marijuana compared to other controlled substances. ATACH—as a representative of its members—seeks to participate in a hearing and formal rulemaking process to the fullest possible extent to provide insights regarding the Proposed Rule’s multifaceted effects on the state-legal, regulated marijuana marketplace. ATACH and its members desire a robust, regulated market for marijuana, and ATACH’s participation would offer expert analysis into the risks the illicit market presents to cannabis businesses, consumers, and the public. The illicit market represents a significant issue raised by the Proposed Rule precisely because it is “not subject to any standards or oversight.” *Id.* at 44,606. ATACH would detail the current regulatory structures applicable to the state-legal marijuana marketplace and demonstrate that the variability of “product standards and safety requirements” are not nearly as “wide” as the Proposed Rule suggests. *See id.* Among other things, the Proposed Rule directly affects ATACH’s work advocating for a robust, regulated marijuana marketplace. For example, ATACH’s Board of Directors has created a standing committee that handles issues and advocacy regarding marijuana scheduling. The Proposed Rule will cause ATACH to

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expend time and resources to advocate on behalf of its members and to advance a robust, responsible marijuana marketplace. Michael Bronstein, President of ATACH, is leading national efforts to combat the unregulated intoxicating cannabinoid market and is prepared to testify on the public safety imperative of 26 U.S.C. § 280E relief for the state-regulated marketplace.

- ***Practical Consequences:*** DOJ acknowledges that it is seeking comments on “practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks.” Proposed Rule at 44,621. ATACH is prepared to provide expert testimony and documentary evidence on the implications of Section 280E of the Internal Revenue Code on state-sanctioned businesses and the public health and safety consequences of a final rule keeping marijuana in schedule I or transferring it schedule II. This is particularly relevant to DEA’s questions about “practical effects of the proposed rule” because a final rule transferring marijuana to schedule III would provide Section 280E tax relief to the regulated industry, allowing it to compete with the untaxed, unregulated illicit marketplace more effectively. If the agency backtracks and decides that marijuana should remain in schedule I or be moved to schedule II, that decision would have significant negative impacts on ATACH and its members. ATACH’s members currently suffer immense tax consequences as a result of 26 U.S.C. § 280E because of marijuana’s placement in schedule I. ATACH’s members also face difficulty in conducting medical research and assisting veterans because of the schedule I designation. Economists retained by ATACH are prepared to testify about the implications of Section 280E relief on small and minority-owned cannabis businesses.

Accordingly, ATACH—as a representative voice of its members—submits this filing to participate to the fullest extent permissible by law in any hearing relevant to this rulemaking that DEA grants. ATACH is also an “interested person” because the Proposed Rule would adversely affect and aggrieve ATACH and its members.

Put simply, the Proposed Rule, if finalized, would directly and adversely affect ATACH and its members. ATACH needs to show only administrative standing, rather than Article III standing, to participate in this administrative proceeding. *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (discussing a lower threshold required for “administrative standing” compared to Article III standing). But regardless, for all the reasons just described, ATACH has standing under both standards. Broad participation in agency proceedings and an expansive understanding of the term “interested person” are often necessary because the agency’s decision-making implicates public policy. *Id.*

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E.

ATACH represents a coalition of active participants in and around the state-legal cannabis industry that are directly and adversely affected by the Proposed Rule. ATACH is thus uniquely situated to assist DEA's administrative decision-making if DEA desires a hearing. ATACH and its members have extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated marijuana marketplace. DEA is actively seeking comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. ATACH is particularly well-suited to provide this insight, as it represents a broad coalition of interests, including (but not limited to) distributors, seed-to-sale technology providers, economic consultants, ingredient and garden care suppliers, financial service providers serving the cannabis industry, non-profit researchers, and veterans groups, among other voices.

No basis exists to deny ATACH's participation if DEA convenes a hearing. In fact, none of the reasons courts have cited to deny a movant's participation in an administrative proceeding apply here. *See Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). Collecting cases, the D.C. Circuit noted that courts had denied participation when (i) other parties to the proceeding adequately represent the would-be participant's viewpoint; (ii) participation would broaden unduly the issues considered or obstruct or overburden the proceedings; or (iii) participation would fail to assist the agency's decision-making. *Id.*

First, no other participant in the rulemaking would adequately represent ATACH's viewpoint.¹¹ ATACH has interests in the rulemaking proceedings distinct from those of DEA. As a broad coalition of member entities, ATACH represents an important and diverse group of interests that can speak to the practical consequences of rescheduling marijuana, the risk profile of marijuana and its favorable comparison to schedule I and II substances, and the risks the illicit market presents to cannabis businesses, among other topics.

Second, ATACH's participation would not unreasonably broaden the issues under consideration in the Proposed Rule or obstruct proceedings. DEA has sought information on the practical consequences of rescheduling. ATACH is prepared to provide that perspective if DEA desires a hearing. And if a hearing is granted, ATACH would abide by requirements and briefing applicable to other participants in the formal rulemaking procedure.

Third, ATACH's participation would benefit the agency's decision-making process if DEA were to grant a hearing. As noted above, ATACH's unique perspective would provide insight into: (i) medical research involving marijuana, particularly as it relates to veterans' access; (ii) effects on members who are minority-owned and small businesses and whose communities have been

¹¹ While this filing is made without knowledge of other participants in the potential ALJ hearing, ATACH provides a unique perspective that would not be cumulative to or adequately represented by other participants if DEA grants a hearing on the Proposed Rule.

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impacted by the War on Drugs; (iii) the impact of new marijuana-specific DEA controls on ATACH's members; (iv) abuse potential and public health risks of marijuana, and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. ATACH is prepared to present expert testimony on these issues, as well as (*inter alia*) marijuana's currently accepted medical use in treatment in the United States, relevant international treaty obligations, and the placement of marijuana on the CSA's schedules.

For all these reasons, if DEA grants a hearing in this matter, ATACH hereby requests the ability to participate in that rulemaking process to the fullest extent permissible by law and participate in that hearing. For the avoidance of doubt, ATACH is not requesting a hearing with this filing, but instead requests the ability to participate in a hearing and ALJ process if DEA grants such a hearing at the request of another interested person.

All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully yours,

/s/ Abdul Kallon

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Enclosures

- Exhibit A: *In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022)
- Exhibit B: Hemp for Victory, *Petition to initiate rulemaking proceedings to deschedule marijuana or, alternatively, to transfer marijuana from schedule I to schedule III, IV, or V, and for joinder in pending rescheduling proceedings* (Nov. 15, 2023)
- Exhibit C: OLC, *Questions Related to the Potential Rescheduling of Marijuana* (Apr. 11, 2024)

Exhibit 2



July 22, 2024

THE ECONOMIC IMPACT OF CANNABIS SCHEDULING REFORM ON SMALL AND MINORITY- OWNED BUSINESSES

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Legal Advisor

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Economic Impact of Cannabis Scheduling Reform on Small & Minority-Owned Businesses 2

July 22, 2024

The Honorable Anne Milgram

Administrator

Drug Enforcement Administration

U.S. Department of Justice

8701 Morrisette Drive

Springfield, VA 22152

**Re: Docket No. DEA-1362; A.G. Order No. 5931-2024; 21 CFR 1308**

The Minority Cannabis Business Association (MCBA) is the first national trade association dedicated to serving the needs of minority marijuana businesses and their communities. Our mission is to empower and support minority entrepreneurs and our constituents by creating an equitable and sustainable marijuana industry. MCBA unites community and industry leaders to drive policy, programming, and outreach initiatives to achieve equity for the people most impacted by marijuana prohibition.

MCBA submits this public comment in response to the Drug Enforcement Administration's (DEA) Notice of Proposed Rulemaking (Proposed

Rule) as published in the Federal Register on May 21, 2024, 89 Fed. Reg. 44,597, in support of the reclassification of marijuana from schedule I to schedule III under the Controlled Substances Act (CSA).



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The economic analysis below is particularly responsive to DEA's request for economic data on the impact of this Proposed Rule on small businesses and pursuant to the Regulatory Flexibility Act, [5 U.S.C. 601 et seq.](#) In the Proposed Rule, DEA and the Department of Justice (DOJ) specifically requested the following:

"[T]his action may have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, [5 U.S.C. 601 et seq.](#) For example, section 280E of the Internal Revenue Code bars businesses from claiming tax deductions for otherwise allowable expenses where the business "consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act)." [26 U.S.C. 280E](#). If marijuana is ultimately transferred to schedule III, section 280E would no longer serve as a statutory bar to claiming deductions for those expenses. In addition, small entities

engaged in research on marijuana may be subject to different research protocols set by DEA if the research is conducted on a schedule III substance rather than a schedule I substance. However, DOJ is currently not in a position to estimate the number of small entities affected by these or other potential effects of this action. DOJ seeks comment and additional information to inform its analysis."¹

As detailed below, economic data indicates this Proposed Rule would positively impact all 42,125 state-issued marijuana licenses, and in particular small and minority-owned businesses.² The excess tax payments imposed as a result of IRC § 280E currently prevent marijuana businesses from deducting ordinary business expenses, resulting in higher taxable income and federal tax expense. Rescheduling would allow marijuana businesses to claim these deductions, aligning tax treatment for these businesses with other sectors of the national economy. This change

¹ Schedules of Controlled Substances Rescheduling of Marijuana, 89 Fed. Reg. 44,597, 44,621 (May 21, 2024).

² Data from state marijuana business regulators as compiled by Whitney Economics, July 2024.



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would lead to substantial tax savings and increased profitability for marijuana businesses, including small and minority-owned businesses. Removing marijuana businesses from the effects of § 280E would also allow regulated marijuana businesses to more easily compete with the unregulated, untaxed market.

“Rescheduling would ... lead to substantial tax savings and increased profitability for marijuana businesses, including small and minority-owned businesses”

Our comprehensive survey data of over 200 marijuana businesses further demonstrates that these small and minority-owned businesses, as well as women-owned businesses, have less access to capital, resulting in greater financial vulnerability. For this reason, the § 280E tax burden drains the limited funds of small businesses more rapidly than the larger pools of funds available to larger corporations. Lifting



this burden provides a disproportionate relief to small businesses. MCBA strongly encourages DEA to publish a final rule moving marijuana to schedule III. While rescheduling benefits small business owners by affording significant tax relief, the majority of our members and constituents would be better served by removing marijuana from the schedule of controlled substances entirely.



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The schedule I status of marijuana, as President Biden has recognized, is part of a “failed approach to marijuana,”³ resulting in deleterious effects across the country, particularly in communities of color and other communities particularly affected by the War on Drugs. Of the 11.8 million arrests in the United States for drug-related offenses since 2011, over 80% involved simple possession.⁴ Arrests for simple possession of marijuana comprise approximately 35% of all drug arrests and 44% of drug possession arrests.⁵ Nearly 17% of all arrests in the United States since 2011 were for simple possession of marijuana.⁶ This emphasis on simple possession enforcement disproportionately affects communities of color, including

members and stakeholders of the MCBA. As President Biden recognized, the classification of marijuana under schedule I has “imposed needless barriers to employment, housing, and educational opportunities.”⁷

>80%

of the 11.8 million arrests for drug-related offenses since 2011 involved simple possession.

**~35%**

of all drug arrests were for simple possession of marijuana.

**~44%**

of all drug possession arrests were for possession of marijuana.



³ Presidential Statement on Marijuana Reform, 2022 Daily Comp. Pres. Docs., 2022 DCPD No. 883 (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/> (hereinafter Statement on Marijuana Reform).

⁴ FEDERAL BUREAU OF INVESTIGATION CRIME DATA EXPLORER, <https://cde.ucr.cjis.gov/LATEST/webapp/#/pages/explorer/crime/arrest>. (set location filter to “National” and year filter to “2021”; then scroll down to Arrests Offense Counts in the United States and set “Include Previous Years” to “Past 10 Years”).

⁵ *Id.*

⁶ *Id.*

⁷ Presidential Statement on Marijuana Reform, 2022 Daily Comp. Pres. Docs., 2022 DCPD No. 883 (Oct. 6, 2022).



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The downstream effects of marijuana's schedule I status are particularly pronounced on Black, Latino, and Indigenous people. Even though there are five times more white than Black citizens in the United States, Black Americans are incarcerated 8.2 times more frequently than white people,⁸ largely due to racial targeting associated with drug prohibition laws. Mass incarceration has left one in nine Black children with an incarcerated parent, compared to one in 28 Latino children and one in 57 white children.⁹ Data from the Current Population Survey shows that between 1960 and 2013, the proportion of Black children living with a single parent more than doubled (from 22% to 55%).¹⁰ While rescheduling will provide significant tax relief to small businesses, only descheduling marijuana can correct the racial injustices of the past.

While descheduling marijuana will provide the fullest economic and criminal justice benefits to Americans affected by the War on Drugs, rescheduling marijuana from schedule I to schedule III will have innumerable benefits for small and minority-owned cannabis businesses. As detailed below, these benefits are demonstrated by a July 2024 comprehensive business condition survey of over 200 marijuana companies and a recent economic analysis of the disproportionate burdens of § 280E on small businesses.



⁸ Human Rights Watch, *Punishment and Prejudice: Racial Disparities in the War on Drugs* (May 2000), <https://www.hrw.org/reports/2000/usa/>.

⁹ Collateral Costs: Incarceration's Effect on Economic Mobility, THE PEW CHARITABLE TR. at 4 (2010), https://www.pewtrusts.org/-/media/legacy/uploadedfiles/pcs_assets/2010/collateralcosts1pdf.pdf.

¹⁰ Kathleen M. Ziol-Guest, et al., *One-Parent Students Leave School Earlier: Educational attainment gap widens*, 15 EDUC. NEXT at 36–41 (Feb. 19, 2015), <https://www.educationnext.org/one-parent-students-leave-school-earlier/>.

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I. Economic Impact

The economic impacts of § 280E relief would be profound. The marijuana industry supports almost half a million jobs, even as schedule I classification and the resulting state-federal conflict presents significant challenges to individual businesses, particularly small businesses.¹¹ Because of § 280E's effects, these businesses have expended an estimated \$2.2 billion in tax overpayments compared to American businesses in other sectors.¹² Under the proposed reclassification to schedule III, these tax overpayments could instead support additional job

creation, help businesses avoid predatory terms when accessing capital, and be reinvested in and strengthen those communities disproportionately harmed by decades of the failed status quo.

Our July 2024 comprehensive survey of marijuana companies demonstrates that marijuana businesses are overwhelmingly small businesses, mirroring national trends seen in the broader economy. Over 99% of businesses in the country are small businesses.¹³ Small businesses are the nation's job creators; between 2013 and 2023, small businesses contributed 55% of total net job creation.¹⁴ Small businesses

¹¹ "Currently, the legal cannabis industry boasts 440,445 full-time jobs." *Why the Cannabis Industry Saw 5.4% Job Growth in 2023*, *Forbes* (April 10, 2024), <https://www.forbes.com/sites/willyakowicz/2024/04/10/why-the-cannabis-industry-saw-54-job-growth-in-2023>.

¹² See *infra* Section I.E.

¹³ Rebecca Leppert, *A Look at Small Businesses in the U.S.*, *Pew Research Ctr.* (Apr. 22, 2024), <https://www.pewresearch.org/short-reads/2024/04/22/a-look-at-small-businesses-in-the-us/#:~:text=Among%20the%20roughly%206%20million,have%20100%20to%20499%20workers>.

¹⁴ U.S. Bureau of Labor Statistics, U.S. Department of Labor, *The Economics Daily*, *Small businesses contributed 55 percent of the total net job creation from 2013 to 2023*, <https://www.bls.gov/opub/ted/2024/small-businesses-contributed-55-percent-of-the-total-net-job-creation-from-2013-to-2023.htm>.



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strengthen local communities, particularly those facing historical discrimination, even providing community health benefits.¹⁵

Reclassifying marijuana to schedule III will permit small marijuana companies to compete fairly and equally with the rest of America's small businesses, leveling the playing field and allowing these businesses to employ more people and strengthen their local communities. The benefits of reclassification to schedule III are born out by empirical evidence from a nationwide survey administered to marijuana business owners at all levels of the supply chain. The results from this survey, detailed in the sections below, are illuminating: the marijuana industry faces significant financial difficulties brought about by the effects of § 280E. But these headwinds would shift substantially with the reclassification to schedule III.

>99%**Of U.S. businesses are small businesses**

A. Survey Methodology

This July 2024 survey was shared with a nationally representative group of businesses in the marijuana industry, including retailers, product manufacturers, wholesalers, and cultivators. Respondents provided demographic information related to their race, gender, and state. In addition, respondents were also asked questions related to their business operations, including (1) whether they hold a marijuana license, (2) the number of states in which they operate, (3) the number of employees, (4) estimated annual revenues, and (5)

¹⁵ SHOBAH RAMANDHAN, et al., *The role of small, locally-owned businesses in advancing community health and health equity: a qualitative exploration in a historically Black neighborhood in the USA*. CRITICAL PUBLIC HEALTH, 33(5), 633–645 (2023), <https://doi.org/10.1080/09581596.2023.2256945>.

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whether they are profitable. Additional survey questions directly targeted the issue of federal taxation, including questions about whether the federal tax code had impacted their business and how they would use federal tax relief if the burdens of § 280E on their business were eliminated.

B. Survey Results

The survey was deployed on June 11, 2024, and closed on July 3, 2024, with 206 responses. Of these 206 responses, 171 were from businesses that directly cultivate, process, manufacture, distribute, test, or sell marijuana. These responses include hundreds of individual licensees across 32 states and Puerto Rico. With such a sample size, this analysis can extrapolate to the entire United States marijuana market with a 95% confidence interval and a +/- 6.5% margin of error. The following results

demonstrate how the state-regulated marijuana industry, primarily composed of small businesses, is struggling under the weight of burdensome federal § 280E taxation. With rescheduling, small and minority-owned marijuana businesses will see billions of dollars in tax relief that can be reinvested in sustainable growth and their local communities.

C. Industry Composition

The state-regulated marijuana industry is primarily composed of small businesses owned and operated by local entrepreneurs. To determine which businesses qualified as “small businesses,” this economic study utilizes the “Small Business Size Standards by NAICS Industry,” established by the Small Business Administration (SBA).¹⁶ Since the North American Industry Classification System (NAICS) does not include

¹⁶ 13 CFR § 121.201.

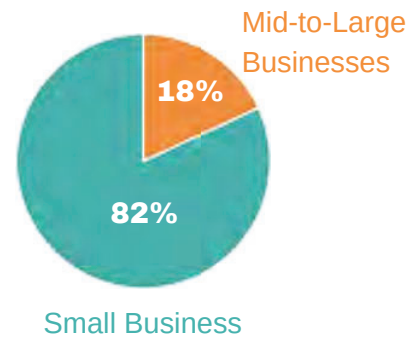


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marijuana businesses within its categorization, this analysis chose industries in each vertical that share important similarities.¹⁷ Based upon this size standard, over 82% of marijuana businesses are classified as small businesses. When the analysis considers companies that hold a retail license, but do not hold a cultivation, processing, or manufacturing license, this figure increases to over 94% of businesses surveyed are small businesses.

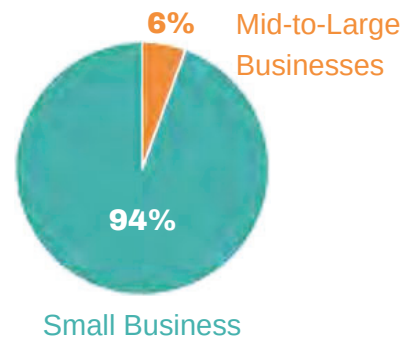


All Licensees



Only Retail

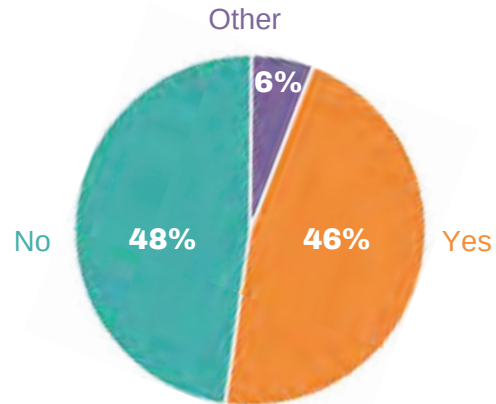
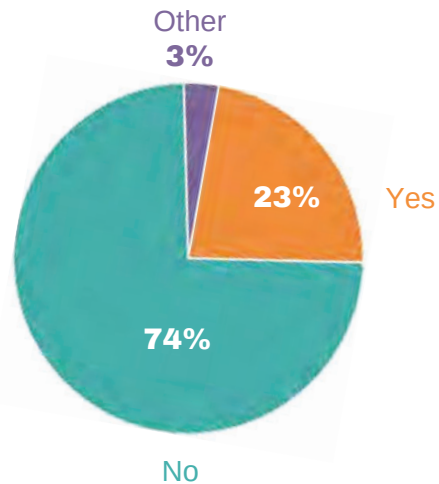
(With or Without Wholesale and Distribution)



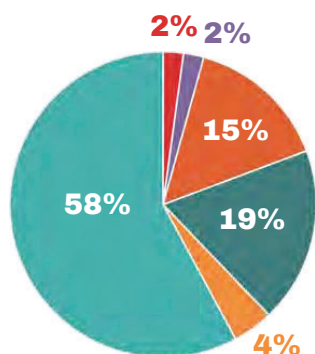
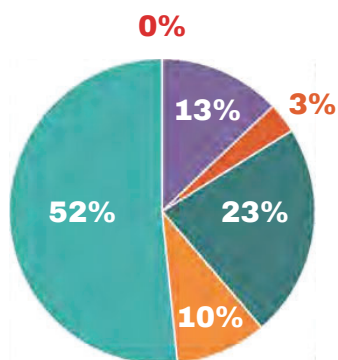
¹⁷ The following NAICS codes were used for each cannabis license type: Marijuana cultivation - (NAICS 111419) Other Food Crops Grown Under Cover & (NAICS 111422) Floriculture Production; Marijuana processing and product manufacturing - (NAICS 311942) Spice and Extract Manufacturing; Marijuana wholesale and distribution - (NAICS 424940) Tobacco Product and Electronic Cigarette Merchant Wholesalers; Marijuana retail stores - (NAICS 459991) Tobacco, Electronic Cigarette, and Other Smoking Supplies Retailers & (NAICS 459999) All Other Miscellaneous Retailers; Marijuana testing facilities - (NAICS 541380) Testing Laboratories and Services. A revenue cutoff was utilized based upon the revenue determinations set forth in 13 CFR § 121.201 for small businesses by NAICS code. For industries where the SBA uses number of employees rather than revenue, the number of employees was used in addition to an upper limit of \$15 million in annual revenue, whereby the business was no longer considered a small business. When the revenue cutoff set by the SBA fell inside one of the revenue categories in our survey, the lower limit was used, resulting in an undercounting of small businesses.

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Small businesses in the state-regulated marijuana industry are much more likely to be owned by women and Black or African Americans than mid-to-large sized businesses. Small marijuana businesses are 46% women-owned and 15% Black or African American-owned. This compares to 23% women-owned and 3% Black or African American-owned for mid-to-large-sized marijuana businesses. While rescheduling will positively impact state-licensed marijuana businesses of all sizes, the fact that a majority of licensees are small businesses results in economic benefits primarily impacting local, small businesses.

**Small Business: Women Owned****Mid-to-Large Business: Women Owned**minoritycannabis.org

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Small Business**Mid-to-Large Business****D. Marijuana Business Outlook**

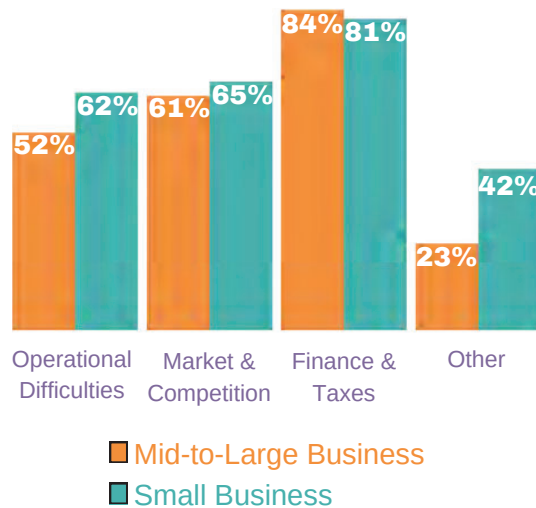
Marijuana businesses are struggling under the weight of heavy federal taxation. Less than 25% of marijuana businesses surveyed report being profitable, and 36% of small businesses surveyed report losing money. Across both small and mid-to-large businesses, over 80% of survey respondents cited finance and tax issues as major issues facing their business. Without tax reform that comes with rescheduling, many small and minority marijuana licensees will go out of business, resulting in major economic losses and unemployment for thousands of local employees. The dissolution of these small and minority marijuana businesses will also serve to fuel the illicit market, where taxes go unpaid.



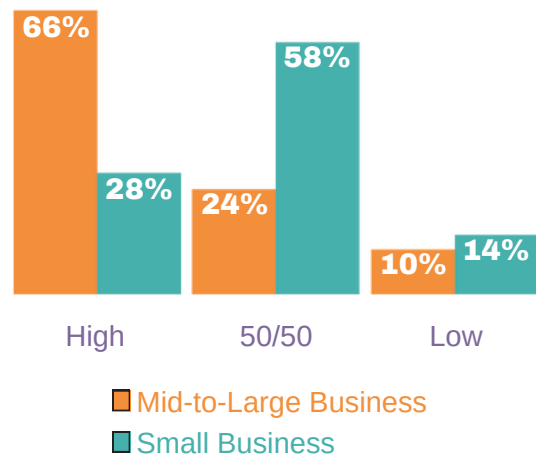
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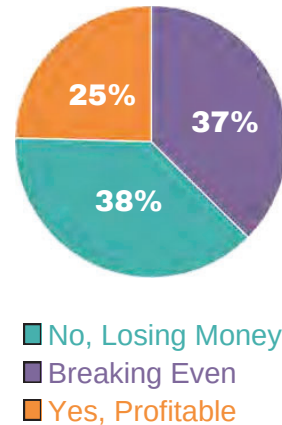
Major Issues Facing Cannabis Businesses



Cannabis Business Confidence in Their Future Success



All Licensees



While small and mid-to-large-sized businesses face similar issues, they are in very different financial positions. Compared to larger-sized companies, small businesses often lack access to capital, which is necessary to pay debts and reach profitability. While 66% of mid-to-large-sized cannabis businesses have high confidence in their future success, that number is only 28% for small businesses. Rescheduling will not only help to improve market confidence, but most importantly, it will provide a necessary boost to profitability that will keep thousands of small businesses solvent and skilled workers employed.

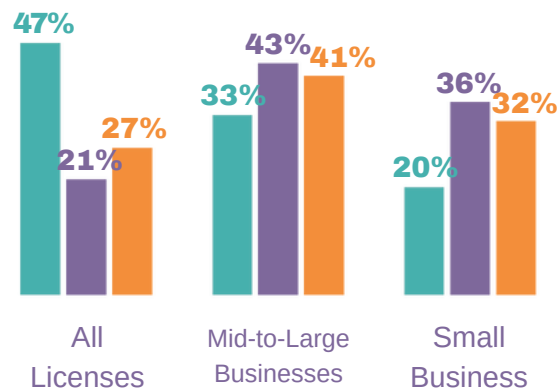
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E. Benefits of § 280E Reform

The July 2024 survey indicates that low margins combined with heavy federal business taxation have steadily eroded profitability. Overall, 27% of survey respondents are profitable, 41% broke even, and 32% are losing money. Finances are much more dire for small marijuana business as only 21% of those surveyed are profitable, 43% broke even, and 36% are losing money. A major driver in these numbers is the inability to take ordinary business deductions because of § 280E, particularly at the retail level, where the effective tax rate is the highest of all marijuana business sectors at 52.5%. The marijuana industry pays a much higher effective tax rate compared to the standard 21% corporate rate for an average industry.¹⁸

This disproportionately high effective tax rate substantially reduces business cash flow and, in many cases, eliminates profitability. Tax relief from rescheduling would thus benefit many of the 42,125 state-issued marijuana licenses across the country.¹⁹

Marijuana Business Profitability



On a national level, in 2023, state-licensed marijuana businesses paid an estimated \$4.3 billion in federal

¹⁸ Garrett Watson, *Combined Federal and State Corporate Income Tax Rates in 2022*, TAX FOUNDATION (Sept. 27, 2022), "Currently, the legal cannabis industry boasts 440,445 full-time jobs." *Why the Cannabis Industry Saw 5.4% Job Growth in 2023*, *Forbes* (April 10, 2024), <https://www.forbes.com/sites/willyakowicz/2024/04/10/why-the-cannabis-industry-saw-54-job-growth-in-2023>.

¹⁹ Data from state marijuana business regulators as compiled by Whitney Economics, July 2024.

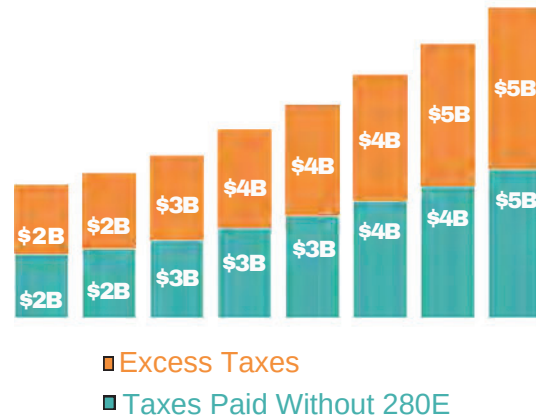


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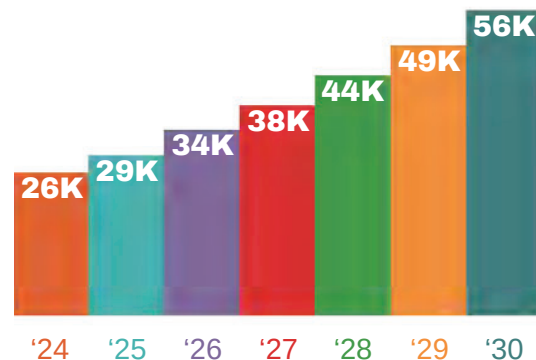
business taxes, \$2.2 billion of which were excess taxes due to § 280E relative to non-marijuana businesses. An additional \$3.3 billion was paid in federal payroll taxes. Without reform, as the market grows, excess marijuana business taxation from § 280E is forecasted to balloon 233% and reach \$5.2 billion by 2030. With rescheduling, this analysis projects significant new hiring and business expansion. Employment opportunities would increase from 25,950 to 55,500 workers from 2024 to 2030, generating an additional \$1.2 billion to \$2.7 billion in wages. With an economic multiplier effect of 2.1X,²⁰ this grows \$2.6 billion to \$5.6 billion in new economic activity, more than offsetting § 280E tax collections from scheduling reform.

“In 2023...marijuana businesses paid an estimated \$4.3B in federal business taxes, \$2.2B of which were excess taxes due to § 280E.”

Taxes Paid With and Without § 280E



Cumulative Job Creation from 280E Relief



²⁰ Whitney, B. (June-July 2016). Cannabis Economics and its Role in Shaping Public Policy [Word and PowerPoint Presentation]. Western Economic Association International 97th Annual Conference, Portland, OR.



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II. Public Safety

Reclassifying marijuana to schedule III, as recommended by HHS, is the most effective action that the federal government can currently take to combat the illicit market and to incentivize a safe and regulated marketplace. State regulatory frameworks for marijuana establish robust safeguards, including lab testing, packaging and labeling standards, and age verification. The illicit market shares none of these consumer protections. If marijuana is not rescheduled, and thousands of small marijuana businesses fail, there is danger that the illicit market will take over, resulting in a public health and safety crisis.

MCBA membership urges DEA to consider this economic data in its analysis of the public safety implications of its Proposed Rule. Many of our members grew up in communities disproportionately impacted by the schedule I

classification of marijuana, incurring social and economic costs, such as family separation and a lack of access to quality healthcare and education. The policy of mass arrests, reliant on the schedule I classification of marijuana, has driven the persistent gap in high school graduation rates between white, Black, and Latino students. In 1980, about 10% of young African American men who dropped out of high school were in prison or jail. By 2008, this incarceration rate had climbed to 37%, a jaw-dropping number when compared to the general population incarceration rate of 0.76%.²¹

Marijuana use did not cause these social harms in minority communities; the failed approach of marijuana enforcement did so, prioritizing mass arrests while ignoring scientific and medical evidence of its low abuse potential. When reviewing HHS's recommendation and this proposed reclassification of marijuana to schedule III, we implore DEA to consider how schedule I has made our communities less safe.

²¹ Bruce Western & Becky Pettit, *Incarceration & social inequality*, *Daedalus: j. am. acad. art & sci.* at 8, 10 (Summer 2010), <https://www.amacad.org/publication/incarceration-social-inequality>



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III. Research

To the extent that reclassification would expand research capacity, we urge DEA to take steps so that minority-serving higher education institutions and institutions like historically Black colleges and universities (HBCUs) are better able to participate in researching marijuana. The overly restrictive paths to research permitted under schedule I have deprived these institutions of grants and resources that could lead to pioneering medical findings.

IV. Conclusion

MCBA and its members and constituents ask DEA to follow the science and reclassify marijuana to schedule III. Reclassification to schedule III will have significant positive economic impacts on small businesses. Our comprehensive survey and detailed economic analysis projects that rescheduling and the resulting § 280E reform would result in the creation of 55,500 jobs by 2030,

generating as much as \$2.7 billion in wages and \$5.6 billion in new economic activity. We therefore encourage DEA to act with deliberate speed in publishing a final rule moving marijuana to schedule III.

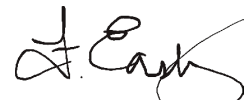
As we suggest in ATACH's petition to intervene, Tahir Johnson stands ready to testify on the economic impact of § 280E relief on small businesses, as well as the impact of descheduling on our members and constituents, in any administrative law judge hearing should DEA grant one.

You may reach us at tahir@minoritycannabis.org and frederika@minoritycannabis.org with any questions.

Sincerely,



Tahir Johnson,
President



Frederika McClary Easley,
Vice President



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Special Thanks To:

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Nicholas Marquiss, Andrew Kline, and Tommy Tobin



Designed By

Ally Schott



²² The views expressed herein are those of the author(s) and not necessarily the views of FTI Consulting, Inc., its management, its subsidiaries, its affiliates or its other professionals. FTI Consulting, Inc., including its subsidiaries and affiliates, is a consulting firm and is not a certified public accounting firm or a law firm.



Exhibit C

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of

Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

Docket No. 22-15

ORDER GRANTING IN PART GOVERNMENT’S MOTION TO DISMISS IN PART

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM), with the docket number DEA-623, titled “Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I.” 87 Fed. Reg. 2376 (2022). The NPRM proposes to place the five tryptamine hallucinogens (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT) in schedule I of the Controlled Substances Act (CSA). *Id.* On January 31, 2022, Panacea Plant Sciences (Panacea) filed a Request for Hearing (RFH). On February 14, 2022, Jason Wallach and Hamilton Morris, Kykeon Biotechnologies Inc. (Mindstate) and Tactogen Inc. (Tactogen), and Amy Rising filed RFHs.

On April 18, 2022, the Government filed its Motion to Dismiss in Part (Government’s Motion) alleging that not all parties requesting a hearing have standing and asking this tribunal to dismiss “any party that cannot establish interested person status for at least one of the substances[.]”¹ Gov’t Mot. at 1. Additionally, the Government requests that this tribunal “limit

¹ The Government concedes that Jason Wallach and Hamilton Morris, who are proceeding jointly, established standing in their RFH with respect to DiPT. Gov’t Mot. at 9. In the April 26, 2022 status conference, counsel for Dr. Wallach and Mr. Morris indicated that they only intended to request a hearing with respect to the proposed scheduling of DiPT and do not wish to challenge the proposed scheduling of the other four tryptamines. Accordingly, Dr. Wallach and Mr. Morris’ standing to challenge the proposed scheduling of DiPT is not challenged herein.

the hearing on this proposed rulemaking to those substances for which an interested person has requested a hearing.” *Id.* at 1-2.

ADMINISTRATIVE STANDING

“The starting point in determining administrative standing should be the language of the statutes and regulations that provide for an administrative hearing, appeal or intervention.” *Koniag, Inc., Uyak v. Andrus*, 580 F.2d 601, 614 (D.C. Cir. 1978) (Bazelon, J., concurring); *see Koniag*, 580 F.2d at 606. The standing analysis is thus an individualized one, within the context of the regulations and the statutory scheme as a whole. *Nichols v. Bd. of Trs.*, 835 F.2d 881, 896 n.108 (D.C. Cir. 1987).

This is a scheduling proceeding under § 811 of the CSA. The regulations governing scheduling proceedings provide that an “interested person” may request a hearing on the proposed scheduling of a substance. *See* 21 C.F.R. § 1308.44. The regulations define “interested person” as “any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant” to 21 U.S.C. § 811. *Id.* § 1300.01. A person requesting a hearing must state “with particularity” his interest in the proceeding. *Id.* § 1316.47(a).

The Agency has not interpreted either “interested person” or “any person adversely affected or aggrieved,” although there are two Agency rulemaking proceedings in which the Agency found a party requesting a hearing did not meet the definition of “interested person.” *See Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013) (denying a request for hearing because a concern that the substance had a large potential for abuse was insufficient to show that the party requesting a hearing was an “interested person”); *Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009) (denying a request for hearing because the party’s statement that “lack of information and inappropriate comparisons to other drugs precluded the scheduling” did not sufficiently establish standing as an “interested person”).

In the absence of an official Agency interpretation, this tribunal looks to general principles on standing. Standing to sue in federal court stems from the Article III case or controversy requirement and thus requires injury-in-fact. *See, e.g., Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338-39 (2016). Moreover, federal courts have put on a “judicial gloss” of prudential standing called the “zone of interests” test limiting who may challenge an agency action. *See Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994). But standing before an administrative agency is

more permissive than before an Article III court. *See Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002) (“Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action.”); *Envirocare, Inc. v. NRC*, 194 F.3d 72, 74 (D.C. Cir. 1999) (“Agencies, of course, are not constrained by Article III of the Constitution; nor are they governed by judicially-created standing doctrines restricting access to the federal courts. The criteria for establishing ‘administrative standing’ therefore may permissibly be less demanding than the criteria for ‘judicial standing.’”); *Nichols*, 835 F.2d at 896 n.108 (“We emphasize that parties may validly participate in agency proceedings even absent standing to obtain judicial review.”); *Koniag*, 580 F.2d at 606 (a party need not be “excluded from participation before the agency if it does not have a sufficient interest to meet Article III requirements for judicial review.”).

Applying the “‘interested person’ concept to parties not entitled to judicial review resists precise legislative or judicial delineation, and requires close scrutiny, in the context of the statutory and regulatory schemes governing the proceedings in which intervention is sought, of the private interest asserted.” *Nichols*, 835 F.2d at 896 n.108 (internal citations omitted). Thus, standing before an agency is not synonymous with standing before a federal court and requires a close examination of the applicable regulations. *Id.*; *see also Koniag*, 580 F.2d at 614. More precisely, the question here is what “adversely affected or aggrieved” requires within the context of the CSA and the limited Agency caselaw for standing in these proceedings.

The Agency has taken the position, in the context of mootness, that it is not bound by Article III. *See, e.g., The Pharmacy Place*, 86 Fed. Reg. 21008, 21008 (2021); *Jeffrey D. Olsen, M.D.*, 84 Fed. Reg. 68474, 68476 (2019).

The subject matter of agencies’ jurisdiction naturally is not confined to cases or controversies inasmuch as agencies are creatures of [A]rticle I. Though agencies must act without arbitrariness, . . . still agencies are generally free to act in advisory or legislative capacities...[which] is obvious in the case of rulemaking[.]

Olsen, 84 Fed. Reg. at 68478 (quoting *Tennessee Gas Pipeline v. Fed. Power Comm’n*, 606 F.2d 1373, 1379 (D.C. Cir. 1979)). While not directly on point, the Agency’s position is instructive given that courts have routinely stated that (with some caveats): “the doctrine of mootness can be described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189-90 (2000)

(internal quotations omitted) (noting exceptions to this rule). Given that the Administrator has rejected the application of Article III in the context of mootness in Agency proceedings, the logical extrapolation of those decisions is that § 1300.01 does not incorporate the requirements of Article III standing.

The Government, however, argues that “adversely affected or aggrieved” applies no differently here than how it has historically been interpreted in federal courts. Gov’t Mot. at 4-5. “The phrase ‘person adversely affected or aggrieved’ is a term of art used in many statutes to designate those who have *standing to challenge* or appeal an agency decision, *within the agency* or before the courts.” *Id.* at 4 n.1 (emphasis in original) (quoting *Dir., Off. of Workers’ Comp. Programs, Dept. of Lab. v. Newport News Shipbuilding and Dry Dock Co. (Newport News)*, 514 U.S. 122, 126 (1995)). The phrase appears in the judicial review provision of the Administrative Procedure Act (APA) and similarly appears in the CSA’s judicial review provision. *See* 5 U.S.C. § 702 (“A person...adversely affected or aggrieved by agency action within the meaning of the relevant statute[] is entitled to judicial review thereof.”); 21 U.S.C. § 877 (“any person aggrieved by a final decision of the Attorney General may obtain review of the decision”). Courts have interpreted the APA’s judicial review provision as requiring a party to show that he is both “injured in fact by agency action and that the interest he seeks to vindicate is arguably within the ‘zone of interests to be protected or regulated by the statute’ in question.” *Newport News*, 514 U.S. at 127 (quoting *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Additionally, courts interpreting the CSA’s judicial review provision have similarly found that it “merely requires that the litigant have Article III standing and prudential standing—i.e., arguably be within the ‘zone of interests.’” *Bonds v. Tandy*, 457 F.3d 409, 413 (D.C. Cir. 2006); *see PDK Lab’ys Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004).

The Government’s interpretation of *Newport News*, however, is too broad. That decision—which involved federal judicial review—stands merely for the proposition that a party challenging an agency decision *in federal court* lacks standing unless the party can establish it had injury-in-fact and fell within the statute’s zone of interests from the very beginning of the case, including before the Agency. *Newport News*, 514 U.S. at 126. But it does not support the proposition that a party must be excluded from *an agency proceeding* if it fails to make that showing. *See Gettman*, 290 F.3d at 434; *Koniag*, 580 F.2d at 606. Similarly unpersuasive are the other cases cited by the Government. While courts have interpreted “adversely affected or aggrieved” as requiring Article

III and prudential standing, those courts were examining statutory provisions establishing standing to seek judicial review before a federal court, not standing before an agency. *See Newport News*, 514 U.S. at 127; *Bonds*, 457 F.3d at 413; *PDK Lab 'ys*, 362 F.3d at 793. As discussed above, courts have repeatedly rejected the presumption that Article III applies to agency proceedings, as has this Agency, in the context of mootness. Moreover, the Government's argument runs counter to the established principle that administrative standing is more permissive than Article III standing. *See Gettman*, 290 F.3d at 434. Accordingly, the Government's argument is unpersuasive.²

The parties find common ground on applying the zone of interests test, which provides that a party requesting a hearing must have an interest in these proceedings and that interest must be “arguably within the zone of interests...” *PDK Lab 'ys*, 362 F.3d at 791 (quoting *Ass'n of Data Processing*, 397 U.S. at 153). The parties requesting a hearing have the burden of proving that they have standing to participate in these proceedings.³ The test is “not meant to be especially demanding[;]” however, where the party is not the subject of the agency action, the party's interests must not be “so marginally related to or inconsistent with the purposes implicit in the statute.” *Clarke v. Secs. Indus. Ass'n.*, 479 U.S. 388, 399 (1987). A party falls “within the zone of interests if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question.” *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998) (citing *First Nat'l Bank & Tr. Co. v. Nat'l Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993)). To be clear, “[j]udicially-devised prudential standing requirements, of which the ‘zone of interests’ test is one, are also inapplicable to an administrative agency...The doctrine of prudential standing, like that derived from the Constitution, rests on considerations ‘about the proper—and properly limited—role of the courts in a democratic society.’” *Envirocare*, 194 F.3d at 75 (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). But, while prudential standing is not necessarily required for administrative standing, absent additional guidance from the Agency, the zone of interests standard provides an instructive framework to interpret the meaning of “adversely affected or aggrieved.”

² Even if the regulations require injury-in-fact, that would not change the outcome of this case. *See infra* note 4.

³ While 21 C.F.R. § 1316.56 provides that the moving party has the burden of proof, the regulations require that the party requesting a hearing demonstrate their interest in these proceedings at the outset. *See* 21 C.F.R. § 1316.47(a).

For these proceedings, the CSA and, specifically, § 811 establish the zone of interests. The overall purpose of the CSA is “to protect the public from the deleterious effects of the illegitimate use and distribution of controlled substances.” *Bonds*, 457 F.3d at 415; *see Gonzales v. Oregon*, 546 U.S. 243, 250 (2005) (the CSA was enacted with “the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances”). To accomplish its purpose, “the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the [CSA’s] five schedules.” *Gonzales*, 546 U.S. at 250. Section 811 regulates how substances may be added, removed, or transferred between the five schedules. 21 U.S.C. § 811. The consequence of such action is that a party may be required to obtain a registration to handle a scheduled substance. 21 U.S.C. § 823; *see MD Pharm.*, 133 F.3d at 13 (the CSA “is a quintessential entry-restricting statute.”). As the Government notes, “[r]esearch of controlled substances is within the class of activity regulated by the CSA.” Gov’t Mot. at 8. Therefore, the zone of interests encompassed by § 811 and the CSA as whole includes researchers who would be regulated by the scheduling of a particular substance.

ANALYSIS

For the following reasons, I find that Panacea, Mindstate, and Tactogen have met the regulatory definition of “interested person” and, thus, have standing to participate in these proceedings.⁴ Ms. Rising, however, does not have standing as an “interested person.” I also reject the Government’s general proposition that an “interested person” may only address a tryptamine if it has established standing for that specific tryptamine.

⁴ While not required, the parties requesting a hearing at issue, with the exception of Ms. Rising, can also show injury-in-fact. In its Partial Withdrawal of its Motion to Dismiss in Part (Government’s Partial Withdrawal), the Government concedes that Tactogen can show injury-in-fact. Gov’t Partial Withdrawal at 1-2. Further, as researchers, Panacea, Mindstate, and Tactogen would suffer economic harm if the tryptamines are scheduled because they would have to obtain a registration to continue their respective projects. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

1. Panacea Plant Sciences

In its RFH and Opposition to the Government's Motion, Panacea, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" its interests in these proceedings.⁵ See Panacea RFH at 3; Panacea Opp'n to Gov't Mot. at 2-3. Specifically, Panacea is a biotech company and has been studying, in collaboration with a Canadian company, the five tryptamines and "other similar compounds in order to treat conditions like depression, anxiety, post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI)." Panacea RFH at 1, 3. Panacea started a project with a doctor at the University of Massachusetts to develop medical therapies utilizing the five tryptamines and other compounds, but Panacea discontinued the project due to the "the potential of conflict and future scheduling." Panacea Opp'n to Gov't Mot. at 2. Additionally, Panacea has patent filings that cover the five tryptamines. *Id.* at 3. Panacea is also collaborating and contracting with other companies and universities to study the five tryptamines and develop therapies, so scheduling the tryptamines will require Panacea to apply for both a manufacturing and research DEA registration. *Id.* at 2-3. Obtaining a registration will be costly for Panacea and cause delays in its research and projects. *Id.*

Panacea meets the regulatory definition of "interested person" under the CSA, as scheduling any or all of the five tryptamines will adversely affect its interests and Panacea's interests fall within the CSA's zone of interests. Panacea falls within the zone of interests because it would be regulated by the scheduling of the five tryptamines; Panacea has ongoing research and projects involving the five tryptamines, and Panacea will be required to obtain a registration to continue its work if the tryptamines are scheduled. See *MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. The potential added cost of obtaining a registration has already forced Panacea to discontinue one project and may require Panacea to discontinue other projects

⁵ The Government argues that Panacea failed to state its interests in its RFH "with particularity," so, if this tribunal does not dismiss Panacea from these proceedings, the tribunal should require Panacea to provide a more detailed statement of its interests. Gov't Mot. at 11. Panacea's RFH provided substantially more detailed information regarding its interests than the two scheduling cases relied on by the Government where the Administrator found that the statements of interest lacked particularity. *Id.* (citing *Placement of Lorcaferin into Schedule IV*, 78 Fed. Reg. at 26703; *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789). Panacea's Opposition to the Government's Motion further supplemented its statement of interests and provided this tribunal with sufficient information to determine whether Panacea is an "interested person." See Panacea Opp'n to Gov't Mot. at 2-3.

or increase the costs of those projects. Since the purpose of § 811 is to determine whether a substance should be scheduled, thereby bringing the substance under the purview of the CSA and restricting access to it, Panacea's interest in continuing to use the five tryptamines directly relates to the purpose of § 811. Therefore, Panacea has standing in these proceedings.

2. Mindstate and Tactogen

In their joint RFH and Opposition to the Government's Motion, Mindstate and Tactogen, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" their interests in these proceedings.⁶ See Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A. Specifically, Mindstate is a research company that "develops psychedelic drug therapies for intractable mental health conditions" and is "currently investigating one or more of the Five Tryptamines in preclinical research." Mindstate & Tactogen RFH at 2. Mindstate is building a database of phenomenological and biochemical data on psychedelic compounds. Mindstate & Tactogen Opp'n to Gov't Mot. at 3. Mindstate must work with tryptamines to complete this project and other projects to develop and bring compounds to market. *Id.* at 4. Tactogen is a public benefit corporation "developing safer, more effective prescription medicines for mental wellness" and is "currently investigating one or more of the Five Tryptamines as part of a program to develop new medicines." Mindstate & Tactogen RFH at 2. Tactogen has had one published patent application under the Patent Cooperation Treaty on the use of tryptamines for mental disorders. Mindstate & Tactogen Opp'n to Gov't Mot. at 4.

Mindstate and Tactogen each qualify as an "interested person" under the CSA because scheduling any or all of the five tryptamines will adversely affect each of their interests and such interests fall within the zone of interests.⁷ Mindstate and Tactogen fall within the CSA's zone of interests because they would be regulated by the scheduling of the five tryptamines. See *MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. Both companies would

⁶ The Government makes the same argument, as it did with respect to Panacea's RFH, that Mindstate and Tactogen's RFH lacked particularity. See *supra* note 5; Gov't Mot. at 12-13. Mindstate and Tactogen's RFH provided enough detail, and their Opposition to the Government's Motion further supplemented their statement of interests to determine if they are an "interested person." See Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A.

⁷ The Government concedes that Tactogen has established standing with respect to 5-MeO-MiPT. Gov't Partial Withdrawal at 1-2. The Government maintains that Tactogen has still not established standing with respect to the other four tryptamines. *Id.*

be required to obtain registrations to continue their respective projects; Mindstate's development of compounds for mental health conditions and Tactogen's development of therapies for mental wellness would be regulated by the CSA if the five tryptamines are scheduled. Like Panacea, Mindstate and Tactogen's interests in using the tryptamines directly relate to the purpose of § 811. Therefore, Mindstate and Tactogen have standing in these proceedings.

3. Amy Rising

In her RFH, Ms. Rising stated that the proposed scheduling of the five tryptamines "would result in barriers to research and the denial [of] life-saving healthcare to US patients" and that they should be placed in schedule V, not schedule I. Rising RFH at 1-2. In her Opposition to the Government's Motion, Ms. Rising stated that she met with the "senate DEA liaison and senate judiciary counsel at their request to discuss the upcoming renewal of the Fentanyl Analogues" several times between August and December 2019. Rising Opp'n to Gov't Mot. at 1-2. Additionally, the Food and Drug Administration "declared psilocybin a 'breakthrough therapy' for treatment-resistant depression." *Id.* at 1. Ms. Rising further indicated that the "National Institute on Drug Abuse Director" stated that obtaining a schedule I DEA registration is administratively challenging and time consuming, so scientists may be deterred from researching schedule I substances. *Id.* at 2. Ms. Rising concluded that she has interests in the scheduling status of the five tryptamines and placing them in schedule I will "impose greater burdens on research, create barriers to access and impose undue difficulty on policy makers..." *Id.*

Ms. Rising has failed to establish her interest in these proceedings. She has provided no information as to what her specific interest is, such as her career or credentials; rather, she simply asserts that she is interested. *See id.* at 2 ("Amy Rising has provided the example of her work and interests in the scheduling status of" the five tryptamines). The only example she has provided of her work is meetings with government officials regarding psilocybin and the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 S. 3201, 116th Cong. (2020), but she does not explain how the meetings related to the five tryptamines, let alone her role and purpose in those meetings. *See id.* She argues that scheduling the five tryptamines in schedule I will create barriers to research but offers no information as to how or why she is affected by potential barriers for research. *See id.* 2-3.

Ms. Rising's general assertion of interest does not meet the regulatory requirements that she both have an interest in these proceedings and that she state that interest "with particularity."

21 C.F.R. §§ 1300.01(b), 1316.47(a); *see Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (denying a request for hearing because a person’s generalized concern was insufficient to demonstrate an interest in the proceeding); *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789 (same). Therefore, given Ms. Rising’s failure to show her interest in these proceedings, she does not have standing to appear in these proceedings.

4. Standing as to Individual Tryptamines

The Government argues that this tribunal should further limit standing in two respects: (1) it should only allow a hearing on those tryptamines for which parties have standing; and (2) an “interested person” should only be allowed to contest a tryptamine for which it has established standing. Gov’t Mot. at 6-7. The Government argues that, while the tryptamines are similar and consolidated into one NPRM, there will be five distinct rules. *Id.* The Government cites no support for the proposition that one NPRM and one rulemaking process results in distinct rules.⁸ Additionally, 21 C.F.R. § 1300.01 defines “interested person” as “any person adversely affected or aggrieved *by any rule or proposed rule...*” (emphasis added). There is one proposed rule,⁹ not five, so any person adversely affected or aggrieved by the scheduling of one of the tryptamines has standing to challenge the proposed rule in its entirety.

Moreover, the Administrator opted to combine the five tryptamines into one rulemaking process and did so, in part, because of the similarity of those substances to each other and to already-controlled substances. NPRM, 87 Fed. Reg. at 2378. Additionally, the NPRM (as well as the Department of Health and Human Services evaluations and recommendations) includes scientific references that deal generally with tryptamines and compare the substances to each other and already-controlled substances. *Id.* at 2378-81. On this basis, a wholesale limitation of the parties is unjustified and would prove impractical at the merits hearing; it would be incongruous to parse the rulemaking process when the Agency has chosen to proceed under one proposed rule.

⁸ The Government does cite 21 U.S.C. § 811(a)(1); however, § 811(a)(1) provides only that the Attorney General may schedule a substance if he makes findings as to such substance. *See* Gov’t Mot. at 6. Section 811(a)(1) is silent as to standing for an “interested person” to challenge those findings and whether one rulemaking process for multiple substances results in distinct rules or one rule encompassing multiple substances.

⁹ The NPRM also repeatedly states that it is one “proposed action,” not five. *See* NPRM, 76 Fed. Reg. at 2376-78, 2381-82.

Further, even if I were to accept the Government's proposition that each "interested person" must have standing with respect to each tryptamine to fully participate in these proceedings, Panacea, Mindstate, and Tactogen have established standing for all five of the tryptamines. Panacea expressly stated that it is researching the five tryptamines, so scheduling any or all of the tryptamines will adversely affect Panacea. Panacea Opp'n to Gov't Mot. at 2-3. The Government concedes that Tactogen is an "interested person" with respect to 5-MeO-MiPT (Gov't Partial Withdrawal at 1-2), and Mindstate is currently utilizing 5-MeO-MiPT and 4-OH-DiPT (Mindstate & Tactogen Opp'n to Gov't Mot., Ex. A at 2). Both companies are arguably within the zone of interests for the other tryptamines because their research and projects will be limited, as the other tryptamines are analogues or related to hallucinogenic substances that the companies are currently studying. Mindstate & Tactogen Opp'n to Gov't Mot. at 14. In sum, the zone of interests test is not meant to be demanding nor are Mindstate and Tactogen's interests inconsistent with the purpose of § 811. *See Clarke*, 479 U.S. at 399; *MD Pharm.*, 133 F.3d at 12-13. Therefore, I reject the Government's argument to partition the hearing by tryptamine and "interested person."

CONCLUSION

Accordingly, the Government's Motion is **GRANTED IN PART** and **DENIED IN PART**. The Government's Motion is **GRANTED** with respect to Amy Rising and **DENIED** with respect to Panacea, Mindstate, and Tactogen.

Dated: May 6, 2022

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 6, 2022, caused a copy of the foregoing to be delivered to the following recipients:

- (1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
- (2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
- (3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
- (4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
- (5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design;
- (6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com;
- (7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com; and
- (8) Amy Rising, via email at amynicholerising@gmail.com.

Aniayah S. Beckford
Staff Assistant to Judge Wallbaum

Exhibit D

November 15, 2023

Anne Milgram, Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, VA 22152

Re: *Petition to initiate rulemaking proceedings to deschedule marijuana or, alternatively, to transfer marijuana from schedule I to schedule III, IV, or V, and for joinder in pending rescheduling proceedings.*

Dear Administrator Milgram:

The undersigned (“Petitioners”) hereby petition to initiate formal rulemaking proceedings for the issuance of an amendment of a rule or regulation under Section 201 of the Controlled Substances Act (“CSA”) and to repeal a rule under 5 U.S.C. § 553(e). Specifically, Petitioners seek removal of “marihuana” from schedule I. Petitioners seek a rule removing marihuana from control or, in the alternative, transferring marihuana from schedule I to schedule III, IV, or V.

Consistent with the CSA and U.S. Drug Enforcement Administration (“DEA”) regulations, Petitioners attach the following exhibits and incorporate them as part of this petition:

Exhibit A1: The proposed rule in the form Petitioners propose.

Exhibit A2: The alternate proposed rule in the form Petitioners propose.

Exhibit A3: Repealing the definition of “medicinal cannabis” in the form Petitioners propose.

Exhibit B: A statement of the grounds on which Petitioners rely.

Petitioners request that the Administrator promptly notify them of acceptance or nonacceptance of the petition and, if not accepted, the reasons therefor.

Petitioners further request and move that they formally be joined as a party to any marijuana rescheduling proceeding currently pending before DEA, including the pending one

publicly referenced by Secretary Becerra,¹ that their grounds and arguments herein be incorporated into such proceedings, they receive notification of joinder, and that they receive all appropriate notices from the agency regarding the progress of the proceedings.

Finally, Petitioners petition and request repeal of 21 C.F.R. § 1318.02(b), to the extent the U.S. Department of Health and Human Services (“HHS”) recommendation recently received by DEA concludes that marijuana has a “currently accepted medical use in treatment in the United States,” for the reasons stated therein.

Introduction

In more than two-thirds of states, millions use marijuana² in treatment following a recommendation from a licensed physician. Most, if not all, these states have reticulated regimes governing and limiting medical-marijuana use. Every year since 2014, Congress has supported these regimes by approving a spending rider prohibiting the U.S. Department of Justice (“DOJ”) from using appropriated funds to interfere with their enforcement. Indeed, no social issue unites more Americans than medical marijuana. Recent polls show that **91%** of Americans support medical use under these state-law regimes.³ This level of support holds true among our nations’ veterans as well.⁴

And yet, DEA insists marijuana has “no currently accepted medical use in treatment in the United States.”⁵ Rather than apply the statutory text, DEA claims “currently accepted medical use in treatment in the United States” requires meeting a five-part test that it admits cannot be squared with the statute’s plain meaning. Petitioners request that DEA do what the statute commands and remove marijuana from schedule I.

DEA should remove marijuana from the schedules entirely. Across almost half the country, states have opted out of the federal government’s failed prohibitionist regime. Millions of Americans, as a result, are using marijuana non-medically and responsibly under regulated regimes. With even more states opting out each year, marijuana and natural THC products have attained a cultural status akin to caffeine, alcohol, and tobacco. Can marijuana be abused? Absolutely. Should it be regulated? Definitely. Because a significant majority of Americans no

¹ See <https://www.hhs.gov/sites/default/files/signed-ash-to-dea-letter-marijuana.pdf>.

² The statutory term for marijuana is “marihuana.” In discussion, Petitioners use marihuana and marijuana interchangeably.

³ See <https://www.pewresearch.org/fact-tank/2021/04/16/americans-overwhelmingly-say-marijuana-should-be-legal-for-recreational-or-medical-use/>

⁴ See, e.g., <https://www.armytimes.com/veterans/2017/11/02/poll-more-than-90-percent-of-vets-support-medical-marijuana-research/> (over 80% back allowing federal doctors to prescribe).

⁵ See 21 U.S.C. § 812(b)(1)(B).

longer consider marijuana a drug of abuse worthy of DEA's attention, however, it no longer has a legitimate place on the CSA's schedules.

Alternatively, DEA should transfer marijuana to schedule III, IV, or V based on scientific evidence related to its abuse potential and dependence risk. Placing it in schedule II alongside far more dangerous and addictive drugs like fentanyl would do nothing to make Americans safer. If anything, it would serve only to undermine the legitimacy of the federal scheduling regime, making it even harder for the federal government to address urgent national crises like opioid abuse effectively.

Respectfully submitted,



Matthew C. Zorn



Shane Pennington

Counsel for Petitioners Hemp for Victory⁶ and Robert Head

All notices to be sent regarding this petition should be addressed to:

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⁶ Hemp for Victory is a non-profit organization headquartered in Carrollton, TX that focuses on cannabis education and the positive impact of cannabis on the veteran community. See <https://hemp4victory.info/about-us/>.

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November 15, 2023

Exhibit A1 – Proposed Rule

We propose the following: removing “marihuana” from schedule I [21 C.F.R. 1308.11(d)(23)].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

Exhibit A2 – Alternate Proposed Rule

We propose the following: removing “marihuana” from schedule I [21 C.F.R. 1308.11(d)(23)] and placing it in schedule [III, IV, or V].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

ADD: 21 C.F.R. 1308.[13, 14, 15] schedule [III, IV, V]: “... (f) Hallucinogenic substances. (1) ... (3) Marijuana.”

Exhibit A3 – Proposed Rule

The following is the proposed rule:

REMOVE: 21 C.F.R. 1318.02(b)

Exhibit B – Statement of Grounds**I. The Schedule I Factors****a. Marijuana has a “currently accepted medical use in treatment in the United States.”**

As of April 2023, at least 38 states, the District of Columbia, and 4 of 5 territories (Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands) have legalized medical marijuana. According to the plain and ordinary meaning of “accepted medical use in treatment,” marijuana has a currently accepted medical use in treatment in the United States. In addition, because marijuana has an accepted medical use, the U.S. Pharmacopeia is currently in the process of establishing a monograph for cannabis (including marijuana) for medical use.

In the past, to determine whether a drug lacks a “currently accepted medical use in treatment in the United States”—the second required finding for placement in schedule I, *see* 21 U.S.C. § 812(b)(1)(B)—DEA has applied a five-part test of its own making:

1. the drug’s chemistry must be known and reproducible;
2. there must be adequate safety studies;
3. there must be adequate and well-controlled studies proving efficacy;
4. the drug must be accepted by qualified experts; and
5. the scientific evidence must be widely available.

See 81 Fed. Reg. 53688, 53700 (Aug. 12, 2016) (citing *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)). *See also, e.g.*, 86 Fed. Reg. 60,761 at 762 n.5 (Nov. 4, 2021) (“[A] drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test[.]”).

For at least the reasons stated by the petitioners in *Sisley v. DEA* (**Ex. 1**), which Petitioners incorporate here by reference, DEA’s five-part test is unlawful. Most prominently, the test interprets § 812(b)(1)(B) in way that renders § 812(b)(1)(C) superfluous—a red flag that its interpretation cannot be right. *See, e.g., Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995) (courts avoid interpretations that “render[] some words altogether redundant”). This third requirement for placing a substance in schedule I expressly demands a finding regarding a substance’s safety for use. *See* 21 U.S.C. § 812(b)(1)(C). Given all this, DEA’s insistence that the second requirement (a lack of “currently accepted medical use”) must also hinge in part on proof of safety for use makes no sense.

As Judge Watford explained after reviewing petitioners’ arguments in *Sisley*:

[I]n an appropriate case, the Drug Enforcement Administration may well be obliged to initiate a reclassification proceeding for marijuana, given the strength of petitioners’ arguments that the agency has misinterpreted the controlling statute by concluding that

marijuana “has no currently accepted medical use in treatment in the United States.” 21 U.S.C. § 812(b)(1)(B).⁷

Under any reasonable interpretation of “currently accepted medical use in treatment in the United States” based on the ordinary public meaning of those terms, DEA *must* reschedule marijuana.⁸

First, in more than two-thirds of the country, according to state law, marijuana use in treatment is accepted medical practice. *See, e.g., Conant v. McCaffrey*, 2000 WL 1281174, at *14 (N.D. Cal. Sept. 7, 2000) (court applying plain and ordinary meaning to conclude that marijuana is a medically acceptable form of treatment in California and seven other states). State law, not DEA preference, determines what is legitimate medical practice in the United States, a reality DEA itself has acknowledged. In the opioid-prescription context, for example, DEA has emphasized that it

does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies ... collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower.

71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006). No doubt, the evidence will show that medical professionals have recommended marijuana for their patients under duly enacted state laws.⁹ *See also, e.g., United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016) (“no rational basis to conclude” that marijuana is not being currently used for medical purposes).

United States v. Moore, 423 U.S. 122, 141 (1975) is instructive. There, the Supreme Court explained that “provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits.” *Id.* The terms of the CSA reflect a congressional intent to align “accepted medical use” with accepted standards of professional practice as determined by state law. Here, it is accepted medical practice for physicians to recommend marijuana use for treatment of certain conditions, such as ameliorating chemotherapy’s side-effects.

⁷ Judge Watford is not alone in flagging DEA’s misinterpretation of the CSA. At oral argument in *Washington v. Barr*, 925 F.3d 109 (2d Cir. 2019), Judge Rakoff did as well. *See* <https://ww3.ca2.uscourts.gov/decisions> (oral argument recording).

⁸ Indeed, because the five-part test as it stands is unlawful, we also ask that it be repealed or amended. 5 U.S.C. § 553(e).

⁹ *See, e.g.,* <https://www.cbsnews.com/news/survey-76-percent-of-doctors-approve-of-medical-marijuana-use/> (New England Journal of Medicine Poll: 76% of votes in favor of the use of marijuana for medicinal purposes); https://www.safeaccessnow.org/survey_majority_of_us_doctors_support_medical_marijuana_legalization (citing polls); <https://www.liebertpub.com/doi/10.1089/can.2020.0165> (almost 70% of clinicians believe cannabis has medicinal uses).

Second, recognizing that marijuana has a currently accepted medical use, the U.S. Pharmacopeia in September 2022 published a proposed *Cannabis* Species Inflorescence monograph in the Herbal Medicines Compendium. The inclusion of cannabis in the U.S. Pharmacopeia is imminent.¹⁰

These circumstances establish a currently accepted medical use beyond cavil. As discussed in *Sisley*, during congressional hearings, the CSA’s drafters explained that “you don’t have to be a doctor to find out whether or not it has an accepted medical use in the United States or not” and the issue “is not something that you are going to create research on.”¹¹ An agency memo drafted shortly after the CSA’s passage (**Ex. 3**) underscores the point:

As the situation stands presently, there is no medical use for marihuana in the United States. The Food and Drug Administration has not granted a New Drug Application for its use in medicine; ***marihuana is not listed in the United States Pharmacopeia***, the National Formulary, the American Drug Index, 1972, Drugs of Choice, 1972, or Physicians Desk Reference, 1972. In fact, both the United States Dispensatory and Remington’s Pharmaceutical Sciences conclude that there is no rational or indispensable therapeutic use for marihuana in modern medicine.

This text, written around the time the CSA was enacted, focuses on the plain meaning of the relevant statutory language and makes the proper § 812(b)(1)(B) inquiry unmistakably clear. *See Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731, 1750 (2020) (the law’s ordinary meaning at the time of enactment usually governs). And it does not suggest the five-part test. It instead accounts for evidence establishing acceptance among medical authorities.

In short, the five-part test as an exclusive means to test accepted medical use is unlawful. While FDA approval or satisfying the five-part test clearly suffices to show a currently accepted medical use in treatment, it cannot be *the only* way to make that showing. Here, when more than two-thirds of the states—the traditional and authoritative regulators of the medical practice—have adopted laws specifically allowing a drug to be used to treat specific conditions, DEA has no discretion to ignore the statute’s plain text to conclude that marijuana lacks a “currently accepted medical use in treatment in the United States.”¹²

¹⁰ For substantially similar reasons, 21 C.F.R. § 1318.02(b) should be repealed.

¹¹ Drug abuse control amendments—1970, Hearings, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 1) at 165 (1970).

¹² DEA’s own arguments in *In re: Marijuana Rescheduling* (**Ex. 2**) further support Petitioners’ position. There, DEA emphasized the fact that parties disputed whether states had passed “research statutes” or “treatment statutes.” DEA went on to explain that the reason it advocated for the same standards that FDA uses for medical acceptability was because those same standards “permeated themselves into the medical community and part of them have been incorporated into the standards that clinicians use to determine whether a drug has an accepted medical use.” *Id.* at 36. In other words, DEA argued that FDA

FDA has long recognized state-level use of a substance in treatment as a viable means of demonstrating “currently accepted medical use in treatment in the United States” for purposes of 21 U.S.C. § 812(b)(1)(B). In 1982, for example, FDA concluded that drugs can “obtain[] ‘accepted medical use’” for purposes of § 812(b)(1)(B) “by virtue of totally intrastate production and use.” 47 Fed. Reg. 28,141, 28,150-51 (June 29, 1982). FDA’s longstanding view is especially important in this context because the question of what constitutes “currently accepted medical use in treatment in the United States” implicates FDA’s scientific and medical expertise as opposed to DEA’s law-enforcement expertise, meaning DEA is statutorily bound to accept its legitimacy. *See* 21 U.S.C. § 811(b) (“The recommendations of the Secretary [and their delegee, FDA] to the Attorney General [and their delegee, DEA] shall be binding on the Attorney General [and his delegee, DEA] as to such scientific and medical matters . . .”).

On this point, the Supreme Court’s decision in *Gonzales v. Oregon* is instructive. 546 U.S. 243, 258 (2006). There, the Court rejected the interpretation of the CSA as authorizing the Attorney General to “declar[e] illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.” *Id.* at 245. Because the CSA refutes the notion that Congress intended to delegate to the Attorney General any authority to make binding judgments regarding the practice of medicine or science, the Court held the Attorney General’s views on what constitutes a “legitimate medical purpose” were not authoritative. *Id.*

Addressing this question directly, the Supreme Court emphasized that “[i]n the scheduling context,” the CSA requires DEA to yield to FDA’s views on scientific and medical matters:

The CSA allocates decision[]making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary’s recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. 21 U.S.C. § 811(b). *See* H.R.Rep. No. 91–1444, pt. 1, p. 33 (1970), U.S. Code Cong. & Admin. News 1970, pp. 4566, 4600 (the section “is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of the Department of Health, Education, and Welfare”).

Id. at 265. In fact, long before *Oregon*, DEA itself acknowledged that it had no delegated authority to make medical judgments or to regulate the practice of medicine, 57 Fed. Reg. at 10,505:

Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to

standards serve as a proxy or indirect evidence for what the medical community accepts as having medical use when direct evidence of accepted medical use is not available.

determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word “accepted” out of the statutory standard.

b. There is an accepted safety for use of marijuana under medical supervision.

For similar reasons, there is an accepted safety for use of marijuana under medical supervision. Contemporary evidence (including peer-reviewed clinical research) shows, for example, that marijuana use is generally safe.¹³ Such research also does not associate medical-marijuana use with severe adverse events, even among those with mental disorders.¹⁴

Indeed, marijuana not only can be safely used under medical supervision, but in many instances, doctors recommend marijuana over approved pharmaceuticals as a safer, less-addictive alternative. For example, there is “substantial evidence that cannabis is an effective treatment for chronic pain in adults.”¹⁵ Some states permit marijuana recommendations in lieu of opioid prescriptions. There is substantial evidence that medical marijuana can substitute for opioid-based pain medications.¹⁶

c. Marijuana does not have a high potential for abuse.

In studies ranking the relative harmfulness of drugs, marijuana consistently ranks below drugs in schedules I and II.

In a study by Bonnet, Udo et al. (2020) entitled “Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction

¹³ See, e.g., Bonn-Miller, Marcel O et al. “The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial.” *PLoS one* vol. 16,3 e0246990. 17 Mar. 2021

¹⁴ See, e.g., Hoch E, Niemann D, von Keller R, Schneider M, Friemel CM, Preuss UW, Hasan A, Pogarell O. How effective and safe is medical cannabis as a treatment of mental disorders? A systematic review. *Eur Arch Psychiatry Clin Neurosci*. 2019 Feb;269(1):87-105. doi: 10.1007/s00406-019-00984-4. Epub 2019 Jan 31. Erratum in: *Eur Arch Psychiatry Clin Neurosci*. 2019 Apr 5; PMID: 30706168; PMCID: PMC6595000.

¹⁵ National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* at 87-90 (2017); Romero-Sandoval, E Alfonso et al. “Cannabis and Cannabinoids for Chronic Pain.” *Current rheumatology reports* vol. 19,11 67. (Oct. 5, 2017) (**Exhibit C**) (concluding that “scientific evidence presented demonstrates that inhaled cannabis is clinically useful for the treatment of chronic (neuropathic) pain, and seems to be safe and tolerable for long-term use under medical supervision”).

¹⁶ E.g., Reiman A, Welty M, Solomon P. Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. *Cannabis Cannabinoid Res*. 2017 Jun 1;2(1):160-166. doi: 10.1089/can.2017.0012. PMID: 28861516; PMCID: PMC5569620.

Medicine Experts,” for example, 30 substances were ranked according to harm to users and others.¹⁷ Cannabis ranked below schedule I and II drugs such as heroin and methamphetamine and alongside schedule III drugs such as benzodiazepines and ketamine. Common experience dictates that marijuana has fewer relative harms than opioids.¹⁸ Compared to benzodiazepines, marijuana also presents a lower potential for abuse and less risk of dependence. Indeed, research suggests medical marijuana can be used to discontinue benzodiazepine use.¹⁹

Other evidence underscores marijuana’s low abuse potential. For example, Dr. Volkow recently stated that to her knowledge, there’s “no evidence” that occasional adult marijuana use has harmful effects. This DEA cannot ignore: Dr. Volkow currently directs the National Institute of Drug Abuse and is an expert in marijuana research having authored dozens of articles on marijuana use, including Zehra, Amna et al. (2018) entitled “Cannabis Addiction and the Brain: a Review”²⁰ and Volkow, Nora D et al. (2016) entitled “Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review.”²¹

d. 21 U.S.C. § 811(d)(1) does not limit DEA’s authority.

For at least the reasons stated by the petitioners in *Sisley v. DEA* (Ex. 1), section 811(d)(1) is unconstitutional. Petitioners hereby incorporate Shane Pennington & Matthew Zorn, *The Controlled Substances Act: An International Private Delegation That Goes Too Far*, 100 Wash. U. L. Rev. (2023) (<https://wustllawreview.org/2023/05/19/the-controlled-substances-act-an-international-private-delegation-that-goes-too-far/>) by reference.

Also, as noted by the agency, even if § 811(d)(1) does apply, DEA has discretion to control marijuana in schedule III, IV, or V, and simultaneously amend its regulations to require a permit to import or export marijuana, as it did with Epidiolex. 83 Fed. Reg. 48,950 (Sept. 28, 2018).

¹⁷ Bonnet, Udo et al. “Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction Medicine Experts.” *Frontiers in psychiatry* vol. 11 592199. 26 Oct. 2020, doi:10.3389/fpsyt.2020.592199.

¹⁸ Lake, Stephanie et al. “Evidence shows that cannabis has fewer relative harms than opioids.” *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* vol. 192,7 (2020): E166-E167.

¹⁹ Purcell, Chad et al. “Reduction of Benzodiazepine Use in Patients Prescribed Medical Cannabis.” *Cannabis and cannabinoid research* vol. 4,3 214-218. 23 Sep. 2019.

²⁰ Zehra, Amna et al. “Cannabis Addiction and the Brain: a Review.” *Journal of neuroimmune pharmacology: the official journal of the Society on NeuroImmune Pharmacology* vol. 13,4 (2018): 438-452.

²¹ Volkow, Nora D et al. “Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review.” *JAMA psychiatry* vol. 73,3 (2016): 292-7. doi:10.1001/jamapsychiatry.2015.3278

II. DEA Should Deschedule Marijuana.

Section 811(b) provides that if the Attorney General determines that the eight-factors listed in 811(c) and “all other relevant data” constitute “substantial evidence that the drug or other substance should be removed entirely from the schedules,” then the Attorney General “shall initiate proceedings for control or removal.” In the case of marijuana, substantial evidence outside of the Section 811(c) factors shows that marijuana should be removed entirely from the schedules and regulated by the states.

Not all drugs of abuse—even addictive ones—are controlled. Caffeine has addictive properties that may lead to physical dependence.²² Caffeine intoxication may result in tachycardia, vomiting, cardiac arrhythmias, seizures, and in extreme doses, death.²³ Caffeine use disorder is a problematic pattern of caffeine consumption characterized by a persistent desire to cut down or control use of the substance along with unsuccessful efforts to do so despite problems caused or worsened by caffeine.²⁴ But caffeine is not scheduled because it is a commonly accepted drug. Most people who use caffeine do so safely every day. Many use caffeine socially, such as by drinking coffee in a café. Some use caffeine as a drug to start their day.

As of 2023, marijuana has achieved a cultural status similar to caffeine and tobacco. Almost 16% of Americans smoke marijuana²⁵—***more than the number of Americans that smoke tobacco cigarettes.***²⁶ The vast majority of marijuana users use marijuana safely with no effects more serious than caffeine. Marijuana is used a social drug. In states where marijuana is legal, there are marijuana cafés or lounges. Marijuana can also be used as a drug before bedtime for sleep. For these reasons, nearly 60% of Americans believe marijuana should be removed from control.²⁷

²² See, e.g., Gilliland K, Bullock W. Caffeine: a potential drug of abuse. *Adv Alcohol Subst Abuse*. 1983-1984 Fall-Winter;3(1-2):53-73. PMID: 6391103.

²³ De Sanctis V, Soliman N, Soliman AT, Elsedfy H, Di Maio S, El Kholy M, Fiscina B. Caffeinated energy drink consumption among adolescents and potential health consequences associated with their use: a significant public health hazard. *Acta Biomed*. 2017 Aug 23;88(2):222-231. doi: 10.23750/abm.v88i2.6664. PMID: 28845841; PMCID: PMC6166148.

²⁴ Addicott MA. Caffeine Use Disorder: A Review of the Evidence and Future Implications. *Curr Addict Rep*. 2014 Sep;1(3):186-192. doi: 10.1007/s40429-014-0024-9. PMID: 25089257; PMCID: PMC4115451.

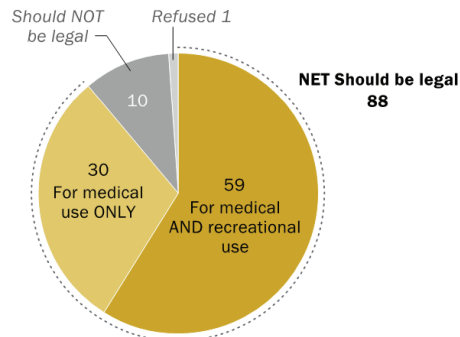
²⁵ <https://news.gallup.com/poll/284135/percentage-americans-smoke-marijuana.aspx>.

²⁶ https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

²⁷ https://www.pewresearch.org/fact-tank/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/ft_2022-11-22_marijuana_01a/.

Just one-in-ten U.S. adults say marijuana should not be legal at all

% of U.S. adults who say marijuana ...



Source: Survey of U.S. adults conducted Oct. 10-16, 2022.

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Equally important, marijuana is treated differently from other drugs of abuse listed in the CSA. Every year Congress prohibits DOJ from spending funds to interfere with state medical marijuana programs. The Attorney General recently confirmed that marijuana enforcement continues to be a low priority for DOJ²⁸—indeed, it is hard to see how DEA could summon the resources necessary to faithfully enforce the CSA as long as marijuana remains a controlled substance. And the President recently pardoned those convicted of simple marijuana possession.

Removing marijuana from the CSA does not mean that the law no longer sees marijuana as a drug that can be abused. The absence of caffeine or tobacco from the CSA's schedules certainly does not mean those drugs cannot be and are not abused. Nor would descheduling marijuana mean that marijuana should not—or would not—be regulated. Rather, descheduling would simply align federal marijuana law with what is by now beyond manifest: for marijuana, the CSA is no longer the appropriate regulatory framework; and DEA is no longer an appropriate regulator.²⁹

III. Alternatively, Marijuana Should be Rescheduled.

Placement in schedule I “does not appear to flow inevitably from lack of a currently accepted medical use.” See *Nat’l Org. for Reform of Marijuana L. (NORML) v. DEA*, 559 F.2d 735, 748 (D.C. Cir. 1977). “[T]he structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence.” *Id.*

²⁸ <https://www.judiciary.senate.gov/imo/media/doc/QFR%20Responses%202-28.pdf>.

²⁹ Many other abused drugs are not scheduled, such as nutmeg (routinely used in cooking) and nitrous oxide (routinely used as whipped cream chargers). Both have substantial non-medical uses and are sold by non-medical providers. The disruption that would be caused by scheduling these substances is “other relevant data” that weighs strongly against control.

As noted above, marijuana has a currently accepted medical use in treatment in the United States. But even if it did not, balancing of medical usefulness along with other considerations would justify rescheduling. In particular, marijuana has a low physical/psychological dependence risk compared to other drugs such as fentanyl.

a. Schedule V or IV

A drug in schedule V has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule IV. Compared to benzodiazepines in schedule IV, marijuana has a low potential for abuse and lower psychological dependence. Marijuana use may produce some level of dependence, and cessation of use may produce withdrawal symptoms.³⁰ But dependence associated with marijuana use and marijuana withdrawal is far less significant than benzodiazepine dependence and benzodiazepine withdrawal.³¹

b. Schedule III

A drug in schedule IV has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule III. As discussed above, marijuana does not have the same potential for abuse as drugs in schedule II such as methamphetamine, cocaine, and fentanyl. Indeed, some evidence suggests cannabis use is associated with a reduced risk of opioid exposure.³²

IV. Conclusion

The Administration has stated that “science will guide” the decision to reschedule marijuana. As important, the decision must be guided by law. Marijuana’s current classification under the CSA as a schedule I substance is legally infirm. For this reason, it must be descheduled or, alternatively, rescheduled.

³⁰ See, e.g., Connor JP, Stjepanović D, Le Foll B, Hoch E, Budney AJ, Hall WD. Cannabis use and cannabis use disorder. *Nat Rev Dis Primers*. 2021 Feb 25;7(1):16. doi: 10.1038/s41572-021-00247-4. PMID: 33627670; PMCID: PMC8655458.

³¹ See Baandrup L, Ebdrup BH, Rasmussen JØ, Lindschou J, Gluud C, Glenthøj BY. Pharmacological interventions for benzodiazepine discontinuation in chronic benzodiazepine users. *Cochrane Database Syst Rev*. 2018 Mar 15;3(3):CD011481. doi: 10.1002/14651858.CD011481.pub2. PMID: 29543325; PMCID: PMC6513394.

³² See, e.g., Socías ME, Choi J, Lake S, Wood E, Valleriani J, Hayashi K, Kerr T, Milloy MJ. Cannabis use is associated with reduced risk of exposure to fentanyl among people on opioid agonist therapy during a community-wide overdose crisis. *Drug Alcohol Depend*. 2021 Feb 1;219:108420. doi: 10.1016/j.drugalcdep.2020.108420. Epub 2020 Dec 17. Erratum in: *Drug Alcohol Depend*. 2021 Apr 1;221:108547. PMID: 33342591; PMCID: PMC8006801.

Exhibit E

(Slip Opinion)

Questions Related to the Potential Rescheduling of Marijuana

The approach that the Drug Enforcement Administration currently uses to determine whether a drug has a “currently accepted medical use in treatment in the United States” under the Controlled Substances Act is impermissibly narrow. An alternative, two-part inquiry proposed by the Department of Health and Human Services is sufficient to establish that a drug has a “currently accepted medical use” even if the drug would not satisfy DEA’s current approach.

Under 21 U.S.C. § 811(b), a recommendation by HHS that a drug has or lacks a “currently acceptable medical use” does not bind DEA. In contrast, the scientific and medical determinations that underlie HHS’s “currently acceptable medical use” recommendation are binding on DEA, but only until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS’s determinations no longer bind DEA, but DEA must continue to accord HHS’s scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS’s findings at any point in the process.

Neither the Single Convention on Narcotic Drugs nor the CSA requires marijuana to be placed into Schedule I or II of the CSA. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific restrictions that follow from a drug’s placement on a particular schedule. As a result, DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA’s regulatory authorities.

April 11, 2024

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Controlled Substances Act (“CSA”)¹ imposes a unified framework for controlling drugs and other substances that are found to pose a risk of abuse.² In doing so, it seeks to balance several, often competing, interests. These interests include ensuring the availability of drugs that “have a

¹ In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, the provisions of which are codified at Chapter 13 of Title 21 of the U.S. Code. The Act comprised several titles, including Title II, which it called the Controlled Substances Act, and Title III, which it called the Controlled Substances Import and Export Act. For ease of reference, we refer to the entire 1970 law as the CSA.

² The CSA applies to both drugs and “other substance[s]” that have been controlled. See 21 U.S.C. § 802(6). For ease of reference, we use the term “drug” to refer to both.

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useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people”; preventing the “illegal importation, manufacture, distribution, and possession and improper use of controlled substances [that] have a substantial and detrimental effect on the health and general welfare of the American people”; and ensuring that the United States complies with “international conventions designed to establish effective control over international and domestic traffic in controlled substances.” 21 U.S.C. § 801(1), (2), (7).

The CSA balances these purposes by placing each drug warranting control into one of five “schedules,” with drugs in Schedule I subject to the strictest regulatory and criminal provisions, and drugs in Schedule V subject to the least strict. *See generally* 21 U.S.C. §§ 821–832, 841–865, 951–971. The CSA further authorizes the Attorney General to add, transfer, and remove drugs from the schedules using formal rulemaking procedures, *see id.* §§ 811, 812, and otherwise grants the Attorney General broad authority to take regulatory action consistent with the Act, *see, e.g., id.* §§ 821, 871(b). The Attorney General has in turn generally delegated these functions to the Administrator of the Drug Enforcement Administration (“DEA”). 28 C.F.R. § 0.100(b).

Marijuana has been a Schedule I drug since Congress enacted the CSA. *See* 21 U.S.C. § 812(c). To reschedule marijuana from Schedule I, DEA would need to determine, among other things, that the drug has a “currently accepted medical use in treatment in the United States” (“CAMU”). *Id.* § 812(b). Since 1992, however, DEA has determined that a drug has a CAMU only if either the Food and Drug Administration (“FDA”) has approved the drug for marketing in interstate commerce under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, or the drug meets a five-part test that tracks the “core standards developed under the FDCA.” 57 Fed. Reg. 10,499, 10,503–04, 10,506 (Mar. 26, 1992). And because FDA has not approved marijuana and DEA has determined that marijuana does not meet its five-part test, DEA has repeatedly rejected petitions to move marijuana to a less restrictive schedule.

On October 6, 2022, President Biden asked the Secretary of Health and Human Services (“Secretary”) and the Attorney General to initiate an “administrative process to review expeditiously how marijuana is scheduled under federal law.” *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/>

Questions Related to the Potential Rescheduling of Marijuana

statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform. The CSA requires the Secretary to provide certain recommendations before the initiation of proceedings to schedule or reschedule a drug, and the statute provides that the Secretary's recommendations "shall be binding" as to certain "scientific and medical matters." 21 U.S.C. § 811(b).

Consistent with this requirement, in 2023, the Department of Health and Human Services ("HHS") recommended that DEA reschedule marijuana to Schedule III. *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023). HHS concluded that, regardless of whether a drug was approved by FDA or satisfied DEA's five-part test, the drug could have a CAMU if it satisfied a new, two-part inquiry. Part 1 of that inquiry asks whether licensed health care providers have "widespread current experience with medical use" of the drug "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine." Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, *Re: Part 1 Analysis* at 1 (July 17, 2023) ("HHS Part 1 Analysis Memo"). If so, Part 2 of the inquiry asks whether there is "some credible scientific support for at least one of the medical uses." *Id.* at 2.

Against this backdrop, you have asked us three questions:³

- (1) If a drug satisfies the two-part inquiry employed by HHS, does that establish a currently accepted medical use under the statute even if the drug has not been approved by FDA and even if the drug does not satisfy DEA's five-part test?
- (2) To what extent do the "scientific and medical matters" referenced in 21 U.S.C. § 811(b), which are binding upon the Attorney General,

³ This opinion memorializes advice we provided you on February 16, 2024. To aid our analysis, we solicited and received written views from HHS and DEA on all three questions and from the State Department on the third question. *See* Memorandum for the Office of Legal Counsel from DEA (Jan. 30, 2024) ("DEA Response"); Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel R. Bagenstos, General Counsel, HHS, *Re: OLC's Request for Views on Issues Related to the Scheduling of Marijuana Under the Controlled Substances Act* (Jan. 29, 2024) ("HHS Response"); Single Convention Requirements for Cannabis and Scheduling Under the Controlled Substances Act (Feb. 12, 2024) ("State Response").

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include the Secretary's evaluation of a drug's currently accepted medical use or any scientific and medical considerations involved in that evaluation?

(3) Does the CSA, including the requirement that the Attorney General control drugs "under the schedule he deems most appropriate to carry out" the United States' "obligations under international treaties, conventions, or protocols in effect on October 27, 1970," *id.* § 811(d)(1), require DEA to place marijuana in either Schedule I or Schedule II to comply with the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407 ("Single Convention")?

As explained in more detail below, we conclude, first, that DEA's current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test.

Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA. We also conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

Third, we conclude that neither the Single Convention nor the CSA requires DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific controls that follow from a drug's placement on a particular schedule. As a result, we conclude that DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA's regulatory authorities.

Questions Related to the Potential Rescheduling of Marijuana

I.

A.

Sections 811 and 812 of the CSA set forth the procedures and standards the Attorney General (and thus DEA) must follow to add a drug to a schedule, transfer a drug between schedules, or remove a drug from the schedules of control. Section 811(a) authorizes the Attorney General to add or transfer a drug to, or remove a drug from, a schedule by issuing a rule “made on the record after opportunity for a hearing” pursuant to the formal rulemaking procedures of the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 553(c), 556, 557. In promulgating such rules, the Attorney General is required to make particular findings, based on substantial evidence, that correspond to the schedule in which the drug is to be placed. 21 U.S.C. §§ 811(a)(1)(A)–(B), 812(b); *see also id.* § 811(b); 5 U.S.C. § 556(d).

Section 812(b) lists the findings the Attorney General must make to place a drug in a particular schedule, with the findings varying by schedule. For example, the Attorney General may place a drug in Schedule I only if the Attorney General finds that the drug “has a high potential for abuse,” 21 U.S.C. § 812(b)(1)(A); “has no currently accepted medical use in treatment in the United States,” *id.* § 812(b)(1)(B); and “[t]here is a lack of accepted safety for use” of the drug “under medical supervision,” *id.* § 812(b)(1)(C). To place drugs in other schedules, the Attorney General must similarly make three findings, except that drugs on the other schedules must have a CAMU (or, in the case of Schedule II drugs, a CAMU with “severe restrictions”). *Id.* § 812(b)(2)(B), (b)(3)(B), (b)(4)(B), (b)(5)(B). Drugs are to be placed in less restrictive schedules as their potential for abuse and likelihood of leading to physiological or physical dependence declines. *Id.* § 812(b)(2)–(5). In the course of making these findings, section 811(c) requires the Attorney General to consider eight medical, scientific, and law-enforcement factors regarding the drug:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.

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- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c).

Although section 811 provides that the Attorney General will issue the final rule to schedule a drug, *see id.* § 811(a), the CSA also assigns a significant role in scheduling decisions to the Secretary. Section 811(b) requires the Attorney General, before initiating a rulemaking proceeding to schedule or reschedule a drug, to request both a scientific and medical evaluation of the drug from the Secretary and the Secretary's recommendation as to the schedule, if any, in which the drug should be placed. The Secretary's recommendations "shall be binding on the Attorney General as to such scientific and medical matters" and the Attorney General is prohibited from controlling a drug if the Secretary recommends that it not be controlled. *Id.* § 811(b). After receiving the views of the Secretary, the Attorney General must initiate rulemaking proceedings if there is sufficient evidence to do so. *See id.*

The legislative history of section 811(b) indicates that its purpose was to place scientific and medical judgments in the hands of the Secretary. The report of the House Committee on Interstate and Foreign Commerce explains that "[c]onsiderable controversy arose" during the drafting process over the scheduling provisions of the bill, in particular "with respect to the proper role of the Attorney General and the Secretary of Health, Education, and Welfare [(‘HEW’)]⁴ in making determinations concerning which drugs should be controlled." H.R. Rep. No. 91-1444, at 22 (1970).

⁴ In 1979, Congress created the Department of Education and changed the name of the Department of Health, Education, and Welfare to the Department of Health and Human Services. Department of Education Organization Act, Pub. L. No. 96-88, §§ 201, 509, 93 Stat. 668, 671, 695 (1979).

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This controversy appears to have stemmed from the fact that the version of the CSA that passed the Senate vested full decisionmaking authority regarding scheduling in the Attorney General alone and required only that the Attorney General obtain the “advice” of the Secretary in connection with scheduling decisions. S. 3246, 91st Cong. § 201(a) (1970); *see* 116 Cong. Rec. 1671, 1672 (1970). During the House’s consideration of the bill, Members of Congress, HEW officials, and scientific and medical professionals raised concerns over the dominant role the Senate bill assigned to the Attorney General, arguing that scheduling decisions largely require scientific and medical expertise and that HEW, not the Department of Justice, had this expertise. *See, e.g., Drug Abuse Control Amendments—1970: Hearings Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Commerce*, 91st Cong. 102–04, 194–95, 199, 550, 557, 580–81 (1970) (“House Hearing”).

Reflecting these concerns, the House version of the bill, H.R. 18583, 91st Cong. (1970), made several changes to what is now 21 U.S.C. § 811(b) that expanded the role of the Secretary and eventually became law. The requirement that the Attorney General obtain “advice” was changed to an obligation to obtain “recommendations” that bound the Attorney General with respect to scientific and medical matters. H.R. 18583, § 201(b). The House bill also added a requirement that the Secretary give a recommendation regarding the schedule in which the drug should be placed and provided that the Attorney General could not control a drug that the Secretary recommended not be controlled. *Id.*

B.

As noted above, Congress classified marijuana as a Schedule I drug when it enacted the CSA in 1970. *See* 21 U.S.C. § 812(c). Shortly thereafter, several organizations petitioned to move marijuana from Schedule I to Schedule V. *See* 37 Fed. Reg. 18,097 (Sept. 7, 1972). The petition was denied three times, but each time on review the United States Court of Appeals for the District of Columbia Circuit remanded for further analysis. *See Nat’l Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654, 661 (D.C. Cir. 1974); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977) (“*NORML II*”); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, No. 79-1660, 1980 U.S. App. LEXIS 13099, at *1 (D.C. Cir. Oct. 16, 1980) (*per curiam*).

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After the third remand, DEA denied the rescheduling petition once more, concluding that marijuana did not have a CAMU. *See* 54 Fed. Reg. 53,767, 53,767, 53,783–84 (Dec. 29, 1989). In reaching that conclusion, DEA relied on an eight-part test for determining whether a drug had a CAMU that included the following three factors: whether the drug was generally available; whether its use was generally recognized in various medical reference works; and whether its use was recognized by “a substantial segment of the medical practitioners in the United States.” *Id.* at 53,783. As before, the petitioners sought review and the D.C. Circuit remanded the case to DEA, concluding that these three factors were arbitrary and capricious because they would be “logically impossible” for drugs in Schedule I to satisfy. *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937, 940 (D.C. Cir. 1991) (“*ACT I*”). But the court held that DEA’s interpretation of the statutory phrase “currently accepted medical use” was “in the main acceptable,” and rejected petitioners’ principal argument that DEA’s interpretation unreasonably relied upon “the absence of demonstrated scientific evidence that the drug is medically useful and safe.” *Id.* at 937, 939. In particular, the court noted that the petitioners had presented only “anecdotal evidence” that “a number of physicians believe marijuana is medically useful.” *Id.* at 939.

On remand a fourth time, DEA again denied the petition, again finding that marijuana did not have a CAMU. 57 Fed. Reg. at 10,499. DEA stated that a drug would have a CAMU if it had been approved by FDA under its “New Drug Application” process or if the drug met the criteria to be recognized by FDA as “Generally Recognized As Safe and Effective.” *Id.* at 10,503 (citing 21 U.S.C. §§ 321(p), 355). In addition, DEA concluded that a drug would have a CAMU if it satisfied a new, five-part test (a revised version of DEA’s previous eight-part test that the D.C. Circuit considered in *ACT I*). *Id.* at 10,504. Under DEA’s new test, a drug has a CAMU if the following elements are satisfied:

- (1) the drug’s chemistry is known and reproducible;
- (2) there are adequate safety studies;
- (3) there are adequate and well-controlled studies proving efficacy;
- (4) the drug is accepted by qualified experts; and
- (5) scientific evidence about the drug is widely available.

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Id. at 10,503–06. All five parts were based on the “core FDCA standards for acceptance of drugs for medical use,” and four were expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval. *Id.* at 10,504–05 (citing 21 U.S.C. §§ 321(p), (w), 355(d); and 21 C.F.R. §§ 314.103(c)(3), 314.50(d)(1), 314.125(b), 314.126). DEA concluded that marijuana did not meet any of these criteria and accordingly denied the request to remove marijuana from Schedule I. *Id.* at 10,507–08.

This time the D.C. Circuit upheld DEA’s decision. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994) (“*ACT I*”). It rejected the petitioners’ “central claim” that DEA’s order rested on an “unreasonable interpretation of the statute.” *Id.* The court noted that it had already concluded in *ACT I* that DEA’s interpretation of the CSA was generally reasonable, and it refused to reconsider that determination. *Id.* at 1134. It further reasoned that none of the criteria in DEA’s new five-part test were “impossible for a Schedule I drug to meet” and that DEA had “corrected the flaws [the court] identified in” *ACT I*. *Id.* at 1135.

Since *ACT II*, DEA has denied several petitions that sought rescheduling of marijuana after applying its five-part test and concluding that marijuana did not have a CAMU. *See, e.g.*, 66 Fed. Reg. 20,038, 20,038 (Apr. 18, 2001); 76 Fed. Reg. 40,552, 40,552 (July 8, 2011); 81 Fed. Reg. 53,688, 53,688 (Aug. 12, 2016); 81 Fed. Reg. 53,767, 53,767 (Aug. 12, 2016). Efforts to challenge these denials in court have proven unsuccessful. *See Ams. for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013); *Krumm v. DEA*, 739 F. App’x 655 (D.C. Cir. 2018). In recent years, however, several jurists have raised serious concerns about DEA’s conclusion that marijuana does not have a CAMU. *See United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016); *United States v. Amalfi*, 47 F.4th 114, 125 (2d Cir. 2022); *Sisley v. DEA*, 11 F.4th 1029, 1036 (9th Cir. 2021) (Watford, J., concurring).

C.

Since 1996, 38 States, the District of Columbia, and four federal territories have legalized the use of medical marijuana. *See* HHS Part 1 Analysis Memo at 4. These laws typically allow the cultivation, sale, and use of marijuana by patients (or their caregivers) whose health care practitioners have recommended that they use marijuana to treat certain, specified

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conditions. *See, e.g.*, Ohio Rev. Code §§ 3796.01(A)(6)(a)–(v), 3796.08(A); N.Y. Cannabis Law §§ 3(18), 30, 31; N.M. Stat. §§ 26-2B-3(F)(1)–(23), 26-2B-3(N), 26-2B-4(A). Conditions can be added to, or removed from, the list of illnesses that may be treated with marijuana, often by (or at the recommendation of) a state’s public health authorities or special boards convened to consider such matters. *See, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c); 410 Ill. Comp. Stat. §§ 130/10(h)(2), 130/45; Or. Admin. Rule 333-008-0090. In each fiscal year since 2015, Congress has also adopted an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *E.g.*, Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, § 531, 138 Stat. 25; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 531, 136 Stat. 4459, 4561 (2022); *see* Cong. Rsch. Serv., R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap* at 26 & n.159 (updated Apr. 7, 2022) (collecting laws).

On October 6, 2022, as noted above, President Biden asked the Secretary and the Attorney General to review how marijuana is scheduled under federal law. As part of its analysis in response to this request, HHS considered whether DEA’s test for determining if a drug has a CAMU was consistent with the text of the CSA. HHS Response at 5–6. HHS agreed that if a drug met the requirements for FDA approval or DEA’s five-part test, the drug would have a CAMU. *Id.* at 8. But it concluded that it would be inconsistent with the text and purpose of the CSA for those standards to be the “sole basis for determining whether a substance has a [CAMU].” *Id.* at 7.

HHS’s analysis instead relied on an additional, two-part inquiry for considering whether a drug has a CAMU. Part 1 of HHS’s inquiry focuses on the extent and nature of medical use. It asks whether there is “widespread current experience with medical use of the substance in the United States by licensed health care practitioners . . . operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part 1 Analysis Memo at 1. HHS further identifies several factors to consider in undertaking this analysis, none being dispositive on its own—specifically, (1) “[w]hether a substantial number of licensed health care practitioners

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have gained clinical experience with at least one specific medical use of the substance under existing and implemented state-authorized programs,” *id.* at 3; (2) “[w]hether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance,” *id.*; and (3) “[w]hether licensed health care practitioners’ clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer term toxicities and potential harms of the substance when used under medical supervision,” *id.* at 5.

Part 2 of HHS’s test focuses on the scientific basis for any identified medical use. It asks whether there is “some credible scientific support for at least one medical use of the substance for which Part 1 is met.” *Id.* at 2. According to HHS, although again not dispositive, factors that count in favor of the conclusion that some credible scientific support exists include (1) whether “favorable clinical studies of the medical use” of the drug, although not FDA approval-level studies, “have been published in peer-reviewed journals” and (2) whether “[q]ualified expert organizations (e.g., academic or professional societies, government agencies) have opined in favor of the medical use or provided guidance to practitioners on the medical use.” Ctr. for Drug Evaluation & Rsch., FDA, *Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act* at 4 (Aug. 28, 2023) (“HHS Part 2 Analysis Memo”). By contrast, factors weighing against the conclusion that such credible scientific support exists include (1) whether “data or information indicates that medical use of the substance poses unacceptably high safety risks for the likely patient population, e.g., due to toxicity concerns”; (2) whether “clinical studies with negative efficacy findings for the medical use have been published in peer reviewed journals”; and (3) whether “qualified expert organizations (e.g., academic or professional societies, government agencies) have recommended against the medical use of the substance.” *Id.* at 4–5.

Applying this two-part inquiry, HHS concluded that marijuana has a CAMU. *Id.* It found that Part 1 of its inquiry was satisfied because more than 30,000 licensed health care practitioners across 43 jurisdictions are authorized to recommend the use of marijuana for more than six million registered patients for at least 15 medical conditions. HHS Part 1 Analysis Memo at 1. HHS also found that Part 2 of its inquiry was satisfied. *See*

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HHS Part 2 Analysis Memo at 7. Although noting that no professional medical organization currently recommends use of marijuana (and that one recommends against its use), HHS concluded after reviewing several studies that there was some credible scientific support that marijuana could be used to effectively treat pain, anorexia, and nausea and vomiting and that using medical marijuana to treat these conditions did not pose “unacceptably high safety risks.” *Id.* at 7. Consistent with this conclusion, and in light of other findings it made, HHS recommended to DEA that marijuana be placed in Schedule III of the CSA.

II.

As discussed above, DEA currently concludes that a drug has a CAMU only if FDA has approved the drug under the FDCA or the drug meets DEA’s five-part test. 57 Fed. Reg. at 10,505–06. HHS agrees with DEA that FDA approval and DEA’s five-part test are sufficient to establish that a drug has a CAMU, *see* HHS Response at 8, and we also agree. To receive FDA approval, a drug must satisfy “rigorous testing and safety reviews” showing that the drug is “both safe and effective.” *Sadoz Inc. v. Becerra*, 57 F.4th 272, 282 (D.C. Cir. 2023). And the entire purpose of FDA’s rigorous approval process is to identify drugs that can be safely and effectively used to treat medical conditions. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133–34 (2000). It would thus make no sense to keep a drug that has met—or could meet—FDA’s standards on Schedule I, which would prevent the drug from being used to treat medical conditions. *See* 21 U.S.C. §§ 829, 841–43.

HHS argues, however, that DEA’s approach to CAMU is impermissibly narrow and that HHS’s two-part inquiry is a permissible way to establish that a drug has a CAMU. You have asked whether, if a drug satisfies the two-part inquiry employed by HHS, that establishes that the drug has a CAMU regardless of whether the drug has been approved by FDA or satisfies DEA’s five-part test. For the reasons that follow, we agree with HHS and conclude that limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA’s five-part test is an impermissibly narrow interpretation of section 812(b) and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU.

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A.

Section 812(b) requires the Attorney General (and thus DEA), in making scheduling decisions under the CSA, to determine whether a drug has a “currently accepted medical use in treatment in the United States.” It is hard to square DEA’s exclusive reliance on FDA approval and its five-part test with this language.

To begin, DEA’s approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard. At the time the CSA was adopted (and as is still true today) the word “accepted” meant “widely used or found” or “generally approved.” *Accepted*, Webster’s Third New International Dictionary 11 (1971); *see also Accepted*, The American Heritage Dictionary of the English Language 8 (1970) (“Generally approved, believed, or recognized.”); *Accepted*, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/accepted> (last visited Apr. 2, 2024) (defining “accepted” to mean “regarded favorably” or “generally approved or used”). And the focus on “medical use” suggests that the relevant inquiry is whether the medical community has accepted that a drug has a “use in treatment.” 21 U.S.C. § 812(b)(1)(B).

Any examination of whether the medical community “accept[s]” that a drug has a “use in treatment,” *id.*, naturally requires an examination of what licensed health care practitioners are actually doing. Practitioners treat patients, after all, and their treatment decisions and clinical experience with a drug (where such experience exists) provide important evidence in determining whether a medical use is accepted. Moreover, an understanding of what the medical community accepts would also naturally require consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners. As the Supreme Court has noted, the CSA “presume[s] and rel[ies] upon a functioning medical profession regulated under the States’ police powers.” *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

But neither FDA approval nor DEA’s five-part test examines whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used. Instead, FDA approval and DEA’s five-part test rely exclusively on certain scientific evidence and the views of some experts and FDA. Simp-

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ly put, ignoring widespread clinical experience with a drug that is sanctioned by state medical licensing regulators when evaluating whether a drug has a CAMU is at odds with the plain meaning of section 812(b).⁵

Limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA’s five-part test also conflicts with the text of section 812(b) by erroneously equating identification of an “accepted” medical use under the CSA with the “approval,” or potential approvability, of the drug under the FDCA. Under the CSA, a substance can only be placed on Schedule I if it lacks *both* a “currently accepted medical use in treatment in the United States” *and* an “accepted safety for use . . . under medical supervision.” 21 U.S.C. § 812(b)(1)(B), (C). By contrast, “the FDCA does not even mention the term ‘medical use,’” *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987), and under the FDCA approval can be denied *either* because the drug is unsafe *or* because it is ineffective, *see* 21 U.S.C. § 355(d)(2), (5). FDA may also deny approval for several other reasons that have nothing to do with medical use, including that the application did not contain the necessary patent information, *see id.* § 355(d)(6), or that the methods used to manufacture, process, and pack the drug “are inadequate to preserve its identity, strength, quality, and purity,” *id.* § 355(d)(3).

Moreover, other CSA provisions confirm that a drug having a CAMU is distinct from it being approved (or approvable) by FDA. Among other things, the CSA elsewhere repeatedly refers to, and in some places explicitly relies on, the FDCA. As an example, 21 U.S.C. § 829 prohibits the dispensing of “prescription drug[s] as determined under the [FDCA]” that are controlled under Schedules II through IV without a prescription from a practitioner, subject to certain exceptions. *See also, e.g., id.* §§ 811(g)(1), 825(e). Congress’s decision to explicitly invoke the FDCA’s standards with respect to some parts of the CSA, but not with respect to whether a drug has a CAMU, strongly suggests that it did not mean to equate CAMU with the standards necessary for FDA approval.

⁵ The First Circuit’s decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), is not to the contrary. *Grinspoon* rejected the argument that Congress meant to privilege the views of “certain members of the medical community” in determining if a drug has a CAMU. *Id.* at 892. The court did not consider, however, the broader understanding of the relevant inquiry that we offer here—i.e., whether the medical community as a whole, including practitioners and regulators (among others), has “accepted” that a drug has a “medical use in treatment.” 21 U.S.C. § 812(b)(1)(B).

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Amendments to the CSA reinforce this conclusion. Congress added the “emergency scheduling” provision to the CSA in 1984. Pub. L. No. 98-473, § 508, 98 Stat. 1837, 2071–72 (1984) (codified as amended at 21 U.S.C. § 811(h)). That provision allows the Attorney General to place certain substances in Schedule I on a temporary basis without following the normal scheduling criteria if “necessary to avoid an imminent hazard to the public safety.” 21 U.S.C. § 811(h). But this authority does not apply where an “exemption or approval is in effect for the [drug] under section 505” of the FDCA—i.e., where FDA allows the drug to be marketed in interstate commerce. *See id.*; *see also* Controlled Substances Analogue Enforcement Act of 1986, Pub. L. No. 99-570, tit. I, subtit. E, 100 Stat. 3207, 3207-13 to -14 (codified as amended at 21 U.S.C. § 801(32)) (exempting drugs that have been approved by FDA from the definition of controlled substance analogue). As the First Circuit has observed, these provisions demonstrate that “absolute reliance on the absence of FDA approval” outside of these limited contexts “would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA.” *Grinspoon*, 828 F.2d at 890.

We recognize that our conclusion that DEA cannot rely exclusively on FDA approval or its five-part test in determining whether a drug has a CAMU is in some tension with the D.C. Circuit’s decisions in *ACT I* and *ACT II*. The record in those cases, however, was materially different from the one contemplated by HHS’s two-part inquiry: the petitioners in *ACT I* and *ACT II* had shown that, at most, a “number of physicians believe[d] that marijuana is medically useful”—evidence that the court twice said was “anecdotal.” *ACT I*, 930 F.2d at 939; *see also id.* (describing petitioner’s evidence as “largely anecdotal”). Indeed, although the court noted that it “ha[d] no grounds” on the record before it “to dispute [DEA’s] premise that without much more complete scientific data American physicians will not ‘accept’ marijuana,” it further observed that DEA’s conclusion would be “more vulnerable” if “virtually all doctors in the United States were vociferous in their espousal of marijuana for medical treatment—notwithstanding scientific uncertainties.” *Id.*; *see also ACT II*, 15 F.3d at 1134–35 (holding that DEA’s interpretation of “currently accepted medical use” was reasonable on law of the case grounds).

In other words, neither *ACT I* nor *ACT II* assessed DEA’s approach in the circumstance envisioned by HHS’s two-part inquiry—where there is

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“widespread current experience with medical use of” a Schedule I drug in the United States by licensed health care practitioners “operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part 1 Analysis Memo at 1. To the contrary, the D.C. Circuit suggested that such circumstances might never occur, as one of its reasons for rejecting DEA’s original eight-part test was that it “appear[ed] impossible” for a Schedule I drug to meet the requirement that there be “[r]ecognition and use of the [drug] by a substantial segment of the medical practitioners in the United States.” *ACT I*, 930 F.2d at 938, 940. Yet with respect to at least one drug—marijuana—subsequent events have shown that a drug can be in Schedule I but still be recommended for medical use by a large number of medical practitioners in the United States. And for the reasons we have explained, when these circumstances exist, the plain text of section 812 mandates that they be taken into account when determining whether a drug has a CAMU.

B.

Having explained why DEA’s construction of the phrase “currently accepted medical use in treatment in the United States” is impermissibly narrow, we turn to why HHS’s two-part inquiry is sufficient to determine whether a drug has a CAMU.

1.

Part II.A explained that, to determine if a drug has a CAMU, section 812(b) requires an analysis of whether, at the present time, the medical community widely understands that a drug has a “use in treatment in the United States.” Although there is no single right answer as to *how* specifically DEA should make this determination, the text of the CSA establishes certain basic parameters to guide the inquiry.

As an initial matter, the definitions discussed above indicate that “accepted” means that something is “*widely* used or found” or “*generally* approved.” *Accepted*, Webster’s Third New International Dictionary 11 (emphasis added). It therefore follows from the word’s plain meaning that “anecdotal evidence” that a “number of physicians believe that [a drug] is medically useful” is not enough to show that the medical community has

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accepted that a drug has a use in treatment in the United States. *ACT I*, 930 F.2d at 939. At the same time, however, “accepted” does not require universal consensus. Rather, it is sufficient if there is a widespread understanding in the medical community that a drug has a use in treatment.

Relatedly, nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition. So long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU. That reflects a basic reality about the medical profession: that “in medicine there is often a range of reasonable treatments[.]” *Young v. United States*, 942 F.3d 349, 352 (7th Cir. 2019).

Moreover, the medical community is not a monolith: It contains individuals and entities with a range of expertise and experiences, including licensed health care practitioners who specialize in certain areas of medicine, generalists with broader expertise, researchers, and regulators. In assessing the views of the medical community, section 812(b)(1)(B)’s emphasis on a “medical use in treatment” indicates that the views of all these constituencies are not equally important in every case. Instead, to determine whether the medical community understands using a particular drug to be within the range of reasonable treatment options, it is the views and practices of the health care practitioners who actually treat a given condition, as well as the regulators charged with enforcing applicable norms of practice, that are often especially relevant.

Finally, we believe a CAMU test must include consideration of the scientific evidence that supports the relevant medical use. This follows from section 811(c)’s requirement that the Attorney General “shall consider” eight factors in making the CAMU determination and other findings under section 812(b), some number of which inherently require consideration of scientific evidence. Although it is unclear exactly how the eight factors listed in section 811(c) correlate to the findings required by section 812(b), it is plain that at least two of those factors—the “scientific evidence of [the drug’s] pharmacological effect, if known” and the “state of current scientific knowledge regarding the drug,” 21 U.S.C. § 811(c)(2), (3)—bear on whether a drug has a currently accepted medical use, and that those factors necessarily require evaluation of scientific evidence. In addition, the requirement to consider “[w]hat, if any, risk there is to the

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public health” and the drug’s “psychic or physiological dependence liability,” *id.* § 811(c)(6), (7), further suggests that an assessment of the available science is an integral part of a CAMU determination. Reviewing the available scientific evidence as part of the CAMU analysis is also consistent with the common-sense intuition that there is an inherent connection between whether the medical community has “accepted” a drug for “use in treatment,” *id.* § 812(b)(1)(B), and the scientific evidence supporting that conclusion. We generally would not expect the medical community to understand that it is reasonable to use a drug to treat a condition unless (as HHS suggests) there is at least some scientific evidence in support of that conclusion—evidence demonstrating, for example, that the drug was effective in treating the condition or does not create unacceptably high safety risks. HHS Part 2 Analysis Memo at 4–5.

2.

We conclude that HHS’s two-part inquiry falls within the basic parameters the CSA provides for establishing that a drug has a CAMU.

Part 1 of HHS’s test requires an assessment of whether health care practitioners are recommending that patients use a drug to treat a medical condition and whether they are doing so in accordance with guidelines issued by entities that regulate the practice of medicine. This approach is consistent with our view that determining whether a drug has a CAMU requires assessing whether there is a widespread understanding in the medical community that using the drug to treat a condition falls within the range of reasonable treatment options. In particular, the actual recommendations of practitioners made under applicable regulatory guidelines constitute strong evidence of whether the medical community understands a drug to be a reasonable treatment option.

The three non-dispositive factors HHS includes in its Part 1 analysis further demonstrate why its test is sufficient. Two of HHS’s factors look, respectively, at whether a “substantial number of licensed health care practitioners” have gained clinical experience with a drug under a state-authorized program and whether a “substantial number” of entities that regulate the practice of medicine have authorized the use of a drug for medical purposes. *See* HHS Part 1 Analysis Memo at 3. In our view, these inquiries provide good evidence of whether there is widespread agreement within the medical community that using the drug would be a reasonable

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treatment option. Similarly, it is more likely that the medical community would widely understand that a drug represents a reasonable treatment option if HHS's third factor is present—i.e., that practitioners' clinical experience with the drug is of a "sufficient extent and duration" to help evaluate whether there are "potential clinical uses," "longer-term toxicities," and "potential harms." *Id.* at 5.

Moreover, Part 2 of HHS's test adequately takes the available scientific evidence into account by asking whether there is some credible scientific support for a least one of the medical uses for which the Part 1 test is met and then providing guidance as to what counts as "credible" scientific support. *See* HHS Part 2 Analysis Memo at 4 (identifying "favorable clinical studies" published in peer-reviewed journals as cutting in favor of the conclusion that the drug has a CAMU); *id.* (identifying data or information that "indicate[s] that medical use of the [drug] is associated with unacceptably high safety risks for the likely patient population" because of "toxicity concerns" as cutting against the conclusion that the drug has a CAMU). Neither section 811(c) nor section 812(b) requires a particular threshold of scientific support to conclude that a drug has a CAMU, and we believe that Part 2's requirement of some credible scientific support is sufficient in a context where health care practitioners have extensive experience with a drug and medical regulators have sanctioned the drug's use. Such clinical experience and regulatory sanction provide alternative sources of information about a drug, thereby making it reasonable not to require the high level of scientific support that might be demanded before a new and untried drug is determined to have a CAMU.

DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions. Specifically, DEA suggests that HHS's emphasis on states is "misplaced" because, in DEA's view, the processes states follow for enacting legislation "are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA." DEA Response at 11. But there is nothing in the text of the CSA that would warrant categorically discounting state practice in this fashion, particularly since doing so would be inconsistent with both the role of states as the central regulators of medical practice, *see Oregon*, 546 U.S. at 270, 274–75, and the fact that they are afforded "great leeway" in adopting measures to "protect public health and safety," *Mackey v. Montrym*, 443 U.S. 1, 17 (1979). Indeed, Congress has already

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recognized the importance of states' views on whether marijuana in particular may be used to treat medical conditions by annually adopting an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *See supra* Part I.C.

In addition, states do often look to scientific and medical judgment in regulating medical marijuana. States typically only allow medical practitioners to recommend medical marijuana to treat specific conditions. *See, e.g.*, Ohio Rev. Code § 3796.01(A)(6)(a)–(v); N.Y. Cannabis Law § 3(18). In some states, practitioners may only recommend the use of medical marijuana after determining that the patient suffers from one of those conditions and that the “potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use.” *E.g.*, Conn. Gen. Stat. § 21a-408c(a); *see also* Fla. Stat. § 381.986(4). Several states have also established processes through which experts can recommend additions to, or removals from, the list of conditions that marijuana may be used to treat, *see, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c)(1), (d); Or. Admin. Rule 333-008-0090(3)(e), (4)(a)—indeed, HHS has informed us that 17 jurisdictions have added conditions that may be treated with marijuana using such processes, *see* HHS Part 1 Analysis Memo at 4. In short, it is simply not the case that state practice concerning medical marijuana is completely divorced from scientific and medical assessment.

III.

As discussed above, the CSA authorizes the Attorney General to place drugs in particular schedules if, after a formal rulemaking, the Attorney General makes certain findings. A particularly important finding is whether a drug has a CAMU, as the Attorney General may only keep or place a drug in Schedule I if it lacks a CAMU. Before initiating a rulemaking proceeding to schedule or reschedule a drug, however, the Attorney General is required to request recommendations from the Secretary that must include whether the drug has a CAMU. *See* 21 U.S.C. § 811(b). The CSA further makes these recommendations binding “as to” certain “scientific and medical matters.” *Id.*

Since HHS has recommended that marijuana has a CAMU, you have asked about the extent to which the “scientific and medical matters” that

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are binding on the Attorney General, and thus DEA, include HHS's CAMU recommendation or any scientific and medical determinations underlying that recommendation. For the reasons that follow, we conclude, first, that HHS's overall CAMU recommendation is not binding on DEA. Second, we conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

A.

We first explain why HHS's overall CAMU recommendation does not bind DEA, starting with the two CSA provisions that govern the CAMU determination. Section 811(a) authorizes the Attorney General to schedule or reschedule a drug if the Attorney General makes certain findings "on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the APA]." Section 812(b) then lays out the relevant findings the Attorney General must make to schedule a drug, including whether the drug has a CAMU.

Taken together, these two provisions commit exclusively to the Attorney General the ultimate responsibility for making the findings required to schedule a drug, including a CAMU finding, and neither mentions the Secretary at all. Instead, the role of the Secretary is addressed in a separate provision of the CSA, section 811(b), which reads as follows:

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The

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recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

This provision makes clear that the Secretary plays a crucial role in the scheduling process. It expressly directs the Attorney General to obtain a scheduling recommendation from the Secretary before initiating the scheduling process and to treat as binding certain “scientific or medical matters.” *Id.*⁶ But section 811(b) does not so much as mention the Secretary’s

⁶ In two recent rulemakings, DEA has stated that HHS’s scientific and medical recommendations only bind DEA with respect to factors (1), (4), and (5) of section 811(c). See 86 Fed. Reg. 29,506, 29,507–08 (June 2, 2021); 86 Fed. Reg. 27,803, 27,805 (May 24, 2021). This view appears to be based on a contrast in section 811(b)’s text: it directs the Secretary to “consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of [section 811(c)],” and “any scientific or medical considerations involved in paragraphs (1), (4), and (5) of [section 811(c)],” with the Secretary’s recommendations being “binding . . . as to such scientific and medical matters.” But section 811(b) highlights the “scientific and medical considerations” in factors (1), (4), and (5) not because HHS should consider the science and medicine underlying only those factors, but rather because those factors all relate to a drug’s abuse potential, the analysis of which Congress understood as resting primarily on law enforcement considerations. See H.R. Rep. No. 91-1444, at 33–36; House Hearing at 718. By comparison, there is no need to direct HHS to consider the “scientific or medical considerations” involved with factors (2), (3), (6), (7), and (8) since those factors involve inquiries that are predominantly, if not entirely, scientific and medical in nature. We thus think it plain that HHS’s recommendations with respect to “scientific and medical matters” are binding for all eight factors listed in section 811(c). See H.R. Rep. 91-1444, at 33; see also *id.* at 22–23 (“[A]ll scientific and

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CAMU recommendation. Instead, section 811(b) expressly identifies a different circumstance in which the Secretary's recommendation concerning an ultimate scheduling determination is dispositive: when the Secretary recommends against controlling a drug. This fact—that section 811(b) identifies a separate scheduling recommendation as binding—makes its silence on the Secretary's CAMU recommendation all the more conspicuous.

Moreover, we do not believe the Secretary's authority to bind the Attorney General with respect to "scientific and medical matters" encompasses a CAMU determination, because such a determination involves judgments that are neither wholly scientific nor wholly medical. For example, as the discussion in Part II indicates, assessing whether a drug has a CAMU may involve, in part, determining whether the extent of medical use present is sufficient to qualify as "accepted" within the medical community. 21 U.S.C. § 812(b)(1)(B). This inquiry is more akin to the application of a legal standard to a set of facts than a judgment necessarily requiring medical or scientific expertise, as it could turn (at least in part) on reasoning or facts that are neither scientific nor medical in nature, such as determining how many states have authorized use of a drug in treating a medical condition. *Cf., e.g., United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (conclusions that are the "product of reasoning processes familiar to the average person in everyday life" do not require specialized expertise); *accord United States v. Vega*, 813 F.3d 386, 394–95 (1st Cir. 2016) (conclusions based on "logic and pattern recognition" do not require specialized expertise). Because a CAMU determination can include elements that fall outside the substantive scope of HHS's authority to bind DEA, HHS's overall determination that a substance has (or lacks) a CAMU cannot be binding.

B.

We next explain why the scientific and medical determinations underlying HHS's overall CAMU recommendations bind DEA, although only until the initiation of formal rulemaking, and why DEA is nonetheless obligated to accord the findings significant deference thereafter.

medical determinations [will be] made by the Secretary of Health, Education, and Welfare[.]" (emphasis added)).

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As a threshold matter, the text and legislative history of section 811(b) demonstrate that the “scientific and medical matters” binding on the Attorney General include the scientific and medical determinations that underlie the Secretary’s CAMU recommendation. *See* H.R. Rep. No. 91-1444, at 33; HHS Response at 10; DEA Response at 16. For example, whether some credible scientific support exists for a particular widespread clinical use, *see supra* Part I.C, is undoubtedly relevant to a CAMU finding—and undoubtedly a “scientific and medical matter.”

The more difficult question, however, is whether HHS’s scientific and medical determinations remain binding throughout the scheduling process—a question on which DEA and HHS hold sharply different views. DEA argues that it “is only bound by HHS’s evaluation as to scientific and medical matters . . . at the beginning of the [scheduling] process,” but “[o]nce rulemaking has begun, DEA can—and must—consider material submitted during the administrative process in reaching a final scheduling determination.” DEA Response at 13; *see also* 76 Fed. Reg. 77,330, 77,334–36 (Dec. 12, 2011) (adopting this position). HHS takes the opposite view, arguing that its scientific and medical recommendations bind DEA throughout the scheduling process, including the formal rulemaking. *See* HHS Response at 10–11.

The CSA is unquestionably hard to parse on this issue. It does not expressly address for what portion of the administrative proceedings HHS’s determinations are binding, nor does it specify how, if at all, such determinations must be considered during the formal rulemaking proceedings. Moreover, what clues the statute does offer point in two opposing directions: On the one hand, the statute requires the Attorney General alone to make the ultimate findings required for scheduling after an on-the-record formal rulemaking, which implies that the Attorney General must consider contrary scientific or medical evidence submitted during that process. *See* 21 U.S.C. § 811(a). On the other hand, the statute makes the Secretary’s scientific and medical determinations “binding” on the Attorney General without expressly limiting the binding nature of those determinations to any particular stage of the scheduling process. *See id.* § 811(b).

Although a close question, we think Congress’s decision to make scheduling decisions subject to a formal rulemaking process ultimately provides the answer. Fundamentally, the proposition that HHS’s determinations bind DEA for the entirety of the scheduling process cannot be

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squared with the nature of the formal rulemaking that section 811(a) requires. Nothing in the CSA limits outside participants to submitting only nonscientific and nonmedical evidence at a rulemaking hearing. Given the possibility that parties may submit contrary scientific or medical evidence, construing section 811(b) to preclude DEA from considering such evidence would be inconsistent with the APA's requirement that rules issued via formal rulemaking be based "on consideration of the whole record . . . and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement . . . [to] consider the whole record."). In short, DEA would not be making a decision based on the "whole record" and "in accordance with the reliable, probative, and substantial evidence," 5 U.S.C. § 556(d), if HHS's determinations barred DEA from considering contrary scientific or medical evidence. Two courts of appeals have suggested in dicta that they view the issue similarly. *See Grinspoon*, 828 F.2d at 890; *Reckitt & Colman, Ltd. v. Administrator, DEA*, 788 F.2d 22, 27 n.8 (D.C. Cir. 1986).

The fact that HHS's recommendations as to certain "scientific and medical matters" do not bind DEA for the entire scheduling process does not mean, however, that they are without effect. Rather, in order to give force to the statutory command that HHS's recommendations "bind[]" DEA, we believe HHS's scientific and medical determinations must be binding until the issuance of a notice of proposed rulemaking ("NPRM"). Up to this point, the formal rulemaking procedures required by section 811(a) are not yet in effect, *see* 21 C.F.R. §§ 1308.43(f), 1316.42(g), meaning there is no conflict between the statutory commands to consider contrary evidence in the record and accord binding effect to HHS's recommendations.

In addition, DEA may not simply cast aside HHS's scientific and medical recommendations once it initiates formal rulemaking proceedings by issuing an NPRM. The categorical use of the word "binding" in section 811(b) suggests that Congress intended HHS's scientific and medical views to at least be a very significant input in the scheduling process. And there would seem to be little reason to make the HHS's views binding at any stage in the process if DEA eventually could discard HHS's determi-

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nations and review scientific and medical matters *de novo*. Cf. *Reno v. Am.-Arab Anti-Discrimination Comm.*, 525 U.S. 471, 487 (1999) (statutes should be read in a manner that “makes sense of the statutory scheme as a whole”).

The legislative history of the CSA supports the view that HHS’s scientific and medical determinations should remain significant throughout the rulemaking process. The House report on the CSA states that Congress intended “all scientific and medical determinations” to be “made by the Secretary,” rather than the Attorney General, and nothing in the legislative history suggests that the Attorney General would be free to make *de novo* scientific and medical judgments once the formal rulemaking is underway. H.R. Rep. No. 91-1444, at 22–23. Indeed, the House report emphasized that section 811 was “not intended to authorize the Attorney General to undertake or support medical and scientific research” for the purpose of scheduling, as that research “is within the competence of [HHS].” *Id.* at 33. And considering this same legislative history, the Supreme Court noted in *Gonzales* that the CSA places “medical judgments” made under the Act in the “hands of the Secretary.” 546 U.S. at 265.

We therefore conclude that, to give proper effect to HHS’s scientific and medical determinations, DEA must continue to accord significant deference to those determinations even once formal rulemaking has commenced and may not undertake a *de novo* assessment of HHS’s findings at any point in the rulemaking process.

IV.

The Single Convention requires parties to impose controls on the cultivation, manufacture, and distribution of various drugs, including “cannabis.”⁷ Among other things, parties to the Convention generally must

⁷ The Convention defines “cannabis” as “the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.” Single Convention art. 1(1)(b). We understand the marijuana in use in the United States to fall within this definition, although the definition of cannabis under the Single Convention is slightly less inclusive than the CSA’s definition of “marihuana,” which includes all parts of the *Cannabis sativa* L. plant with certain exceptions, including mature stalks and sterilized seeds that are incapable of germination. See 21 U.S.C. § 802(16).

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require that manufacturers, distributors, importers, and exporters of cannabis secure a license, Single Convention arts. 29–31; impose quotas on the import and manufacture of cannabis, *id.* art. 21(1); generally prohibit the unauthorized possession of cannabis, *id.* art. 33; and adopt penal provisions making violations of the controls required by the Convention punishable offenses, *id.* art. 36.

Several provisions of the CSA—including sections 801(7), 811(d)(1), 812(b), 823(a), 953(a), and 958(a)—“reflect Congress’s intent to comply with the obligations imposed by the Single Convention.” *Control of Papaver bracteatum*, 1 Op. O.L.C. 93, 95 (1977). Of particular relevance here, section 811(d)(1) provides:

If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures described by subsections (a) and (b) of this section.

The Single Convention entered into force for the United States on June 24, 1967, and was thus “in effect on October 27, 1970.” *Id.* Both our Office and the D.C. Circuit have interpreted section 811(d)(1) to apply to any scheduling action by the Attorney General concerning a drug covered by the Single Convention, including actions to transfer a drug between schedules. Memorandum for John E. Ingersoll, Director, Bureau of Narcotics & Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Petition to Decontrol Marihuana; Interpretation of Section 201 of the Controlled Substances Act of 1970* at 9 (Aug. 21, 1972) (“Lawton Memo”); *NORML II*, 559 F.2d at 747.

Given this, your third question asks whether the CSA or the Single Convention requires marijuana to be placed in Schedule I or Schedule II. This question is one our Office has considered before: in 1972, we concluded that the Convention requires marijuana to be placed in Schedule I or II because placing marijuana in Schedules III, IV, or V would not enable the United States to satisfy its Convention obligations. *See* Lawton Memo at 12–13. In particular, we emphasized that the “quotas on manu-

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facture and importation of a substance required by the Convention could not be maintained under existing statutory authority were marihuana listed in Schedules III, IV, or V.” *Id.*; see also *NORML II*, 559 F.2d at 750–51 (agreeing with the Lawton Memo that Schedule I or II was necessary to meet the United States’ Single Convention obligations). In reaching this conclusion, however, we did not address an issue that both HHS and the State Department now ask us to consider: whether under the CSA the United States can comply with its Single Convention obligations by placing marijuana in Schedule III while “adopting such additional regulations as are necessary for treaty compliance.” HHS Response at 13; State Response at 5–7; see also *NORML II*, 559 F.2d at 752–53 (recognizing the possibility of a similar regulatory approach but taking no position on its availability).

We think this question is a close one. For the reasons that follow, however, we believe that the Single Convention does not require DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule. And consistent with this conclusion, we believe DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA’s regulatory authorities.

A.

To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory “schedule” that specifically authorizes all the necessary restrictions. To the contrary, the Single Convention states that parties will implement the Convention using both “laws and *regulations*.” Single Convention art. 18(1)(b) (emphasis added); see also *id.* art. 4 (referring to the use of “legislative and *administrative measures*” to carry out the Single Convention (emphasis added)). The Single Convention thus appears to explicitly contemplate a scenario in which DEA decides to implement the United States’ obligations through a combination of scheduling and regulatory actions.

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As a result, any limitation on satisfying the United States' Single Convention obligations by supplementing a scheduling decision with regulatory action would have to come from domestic law. Nothing in the CSA, however, states that a drug must be placed into Schedule I or II, or any other particular schedule, to comply with the Single Convention. Nor does the CSA expressly foreclose DEA from satisfying the United States' international obligations with a combination of scheduling and regulatory actions. Rather, section 811(d)(1) directs the Attorney General to “control[]” a drug “under the schedule [the Attorney General] *deems most appropriate*” (emphasis added)—language that signals a broad grant of discretion to the Attorney General (and thus DEA), *see Rex Chainbelt, Inc. v. Volpe*, 486 F.2d 757, 761 (7th Cir. 1973). To be sure, the very same language could be read to mean that DEA must select a schedule without resort to regulatory supplementation. *See* 21 U.S.C. § 802(5) (defining “control” as “to add a drug . . . to a *schedule*” (emphasis added)). But we are reluctant to adopt a restrictive reading of such broad discretionary language, particularly when doing so would preclude DEA from relying on regulatory supplementation to close even relatively minor gaps between a schedule and the United States' international obligations. Indeed, consistent with this reading, DEA has previously placed a drug with the psychoactive chemicals found in cannabis into Schedule V and then imposed additional controls through regulation to comply with the United States' international obligations. *See* 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018).⁸

The CSA's varied, and potentially conflicting, purposes further show why it is appropriate to read section 811(d)(1)'s broad grant of authority in this way. Consider a hypothetical case in which the Single Convention imposes obligations that DEA determines would, absent regulatory action,

⁸ We have taken a similar interpretive approach to section 811(d)(1)'s language specifying that the Attorney General meet international obligations “without regard” to the findings and procedures otherwise required by sections 811(a) through (b) and 812(b). Rather than viewing this language as precluding the Attorney General from following ordinary scheduling practices when international obligations are involved, both our Office and the D.C. Circuit have understood it to allow the Attorney General to identify which schedules would satisfy the United States' international obligations with respect to a particular drug, and then—if more than one schedule would do so—select which schedule to use through the section 811(a) through (b) and 812(b) procedures. Lawton Memo at 10; *accord NORML II*, 559 F.2d at 747.

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require placement on Schedule I or Schedule II, but DEA has also determined that the same drug’s abuse potential, medical usefulness, and health effects warrant placing the drug in Schedule III. *See* 21 U.S.C. §§ 801(1), (2), 812(b)(3). In such a circumstance, reading section 811(d)(1) to allow for consideration of regulatory action allows DEA to conclude that Schedule III is the “most appropriate” schedule by pairing that choice with regulatory actions that ensure compliance with the Single Convention. This enables DEA to comply with the United States’ international obligations while furthering the CSA’s other purposes, thus fulfilling both sets of objectives.

The broad regulatory authority provided by the CSA further suggests that DEA need not rely on scheduling decisions alone to comply with the Single Convention. The CSA authorizes the Attorney General (and thus DEA) both to “promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances,” *id.* § 821, and to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions,” *id.* § 871(b). Courts recognize that broad, discretionary language such as this conveys “extensive” regulatory authority, *Volpe*, 486 F.2d at 761; *see also, e.g., Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1209 (D.C. Cir. 2020)—and, here, the language by its plain terms would seem to encompass regulatory actions that DEA may take to satisfy Single Convention obligations not met by a drug’s schedule alone.

Likewise, the CSA provides the Attorney General with a number of more specific regulatory authorities that DEA may use to enable compliance with particular Single Convention obligations, such as the CSA’s registration requirements. Subject to certain limited exceptions, section 822(a) requires “[e]very person who manufactures or distributes” or “dispenses” a drug to “obtain annually a registration issued by the Attorney General in accordance with rules and regulations promulgated by him,” and section 822(b) further specifies that “[p]ersons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration.” These provisions give DEA the authority to impose a number of controls on a particular drug through registration. Other CSA

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provisions provide similar regulatory authority that could enable a drug on a schedule other than Schedule I or Schedule II to comply with the Single Convention. *See, e.g.*, 21 U.S.C. §§ 823(e), (f), 827(e), 952(b)(2), 953(e)(2), 958(c).

Finally, past practice also supports our conclusion. Specifically, in addition to the example recounted above of DEA imposing additional controls through regulation to comply with the United States' international obligations, *see* 83 Fed. Reg. at 48,952, we understand that DEA previously has relied on a combination of the Attorney General's registration power and general regulatory authority to promulgate extensive safety and security regulations that govern manufacturers and distributors of controlled substances. *See* 21 C.F.R. §§ 1301.71–.77. And our Office has previously read the Attorney General's authority to register manufacturers broadly to permit the imposition of certain controls that would enable compliance with the Single Convention. *See Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs*, 42 Op. O.L.C. ___, at *24 (June 6, 2018) ("*Licensing Marijuana Cultivation*"). These prior regulatory actions indicate that the broad and varied provisions discussed above provide authority that may be used to impose additional controls to satisfy the United States' international obligations.

We recognize that reading the CSA as allowing DEA to use regulatory authorities to close gaps in our compliance with international obligations could be viewed as in tension with certain aspects of the CSA's text and structure. As the Lawton Memo noted, several provisions of the CSA implementing controls required by the Single Convention draw a distinction between Schedules I and II, on the one hand, and Schedules III through V, on the other, in a manner that can be read to suggest that Congress understood the United States would comply with its Convention obligations by placing drugs into Schedules I or II. Lawton Memo at 12; *see, e.g.*, 21 U.S.C. §§ 823(a), (d), (e), 826(a), 842(b), 952(a), (b), 958(a), (c). Moreover, Congress designed the CSA to include five schedules, each with a distinct bundle of requirements and consequences, and allowing DEA to add or subtract controls would arguably have the practical effect of enabling DEA to create new schedules.

These arguments have some force, but they do not carry the day. Since the CSA's enactment, Congress has amended the Act in a manner that indicates the distinction between Schedules I and II and Schedules III

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through V may not be as sharp as the argument above suggests. *See infra* Part IV.B (describing how amendments that added sections 952(b)(2), 953(e)(2), and 827(e) enable the United States to meet certain Single Convention obligations while placing nonnarcotic drugs in Schedule III). In any event, right alongside the provisions that could *impliedly* suggest Schedules I and II will be used to comply with the United States’ Single Convention obligations are provisions that *expressly* grant the Attorney General (and thus DEA) both broad discretion to select the schedule “most appropriate” to satisfy the United States’ international obligations, *see* 21 U.S.C. § 811(d)(1), and broad regulatory authority, *see, e.g., id.* §§ 821, 871(b). And given the plain meaning of the CSA’s regulatory provisions, we do not believe that the CSA’s five-schedule structure can be reasonably understood to preclude DEA from taking at least some regulatory actions to comply with the United States’ international obligations. Indeed, it would be particularly strange to view DEA as so constrained in the context of treaty compliance, given section 811(d)(1)’s express grant of broad discretion to meet international obligations. We therefore believe that something more than such textual and structural inferences are needed to foreclose use of these broad and express statutory grants of regulatory authority to impose additional controls to meet the United States’ international obligations.

Thus, while we take no position on the full extent to which DEA may use the CSA’s broad regulatory authority to impose additional controls to meet international obligations, we do not read the CSA as precluding DEA from ever satisfying the United States’ Single Convention obligations by supplementing scheduling decisions with regulatory action. Rather, we believe that the CSA provides DEA with the discretion to decide, at least in some circumstances, that such a scheduling and regulatory approach is the most appropriate way to strike a balance between the CSA’s varied—and potentially conflicting—purposes of curtailing the improper use of drugs with abuse potential, complying with the United States’ international obligations, and ensuring that medically useful drugs remain available for legitimate purposes. *See* 21 U.S.C. § 801(1), (2), (7).

*Questions Related to the Potential Rescheduling of Marijuana***B.**

We next consider the specific question of whether DEA may comply with the United States' obligations under the Single Convention by supplementing a decision to place marijuana in Schedule III with regulatory action.

As a threshold matter, we understand that, if marijuana were placed on Schedule III, the gap that DEA would need to fill would be modest. To be sure, the Lawton Memo and the D.C. Circuit expressed concern that placing marijuana into Schedule III would create compliance concerns with respect to certain Single Convention requirements. In its submission to us, however, the State Department observed that, even if marijuana were listed in Schedule III, most of the United States' Single Convention obligations would continue to be met. *See* State Response at 4–7. The State Department's view reflects amendments to the CSA that postdate the Lawton Memo (from 1972) and the D.C. Circuit's consideration of the issue (in 1977) and that specifically authorize certain controls required by the Single Convention to be placed on drugs outside Schedules I and II. Given these amendments, many of the gaps previously identified in Single Convention compliance would no longer exist if marijuana were placed in Schedule III.

In particular, the Lawton Memo and D.C. Circuit both pointed to the manufacturing and import quotas required by Article 21 of the Single Convention as potential gaps, *see* Lawton Memo at 12–13, while the D.C. Circuit also identified the estimates and statistical reports required by Articles 19 and 20 and the import and export authorizations required by Article 31(4), *see NORML II*, 559 F.2d at 751 n.71. In 1978, however, Congress enacted 21 U.S.C. § 827(e), which specifically authorizes the Attorney General, among other things, to prescribe measures necessary to comply with the reporting requirements of Articles 19 and 20 of the Single Convention for drugs in any schedule, not just those in Schedules I and II. *See* Psychotropic Substances Act of 1978, Pub. L. No. 95-633, § 104, 92 Stat. 3768, 3772. In addition, in 1984 Congress amended the CSA provisions that implement the import and export permit requirements to specifically authorize the use of permits for a nonnarcotic Schedule III drug. *See* 21 U.S.C. §§ 952(b)(2), 953(e) (enacted by the Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473,

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§§ 521–522, 98 Stat. 1837, 2075–76). If marijuana, a nonnarcotic drug, were placed in Schedule III, we believe these statutory provisions would ensure compliance with both the import quota obligation of Article 21 and the import and export authorization requirements of Article 31(4).

These subsequent enactments address most of the concerns the Lawton Memo and D.C. Circuit identified, with the exception of the manufacturing quota requirements of Article 21 of the Convention. But we believe this remaining gap is addressable using the CSA’s regulatory authorities. Several different authorities appear potentially applicable. A regulation imposing a manufacturing quota on a drug would fall easily within the broad language of section 821, as it would be “relat[ed] to the . . . control of the manufacture” of a drug. 21 U.S.C. § 821. DEA likewise could deem a regulation imposing a manufacturing quota as “necessary and appropriate for the efficient execution of” the CSA function of controlling drugs to meet the United States’ international obligations. *Id.* § 871(b); *see id.* § 811(d)(1). By their plain terms, the CSA’s registration authorities would also give DEA the authority to impose a manufacturing quota on a particular drug through regulation: no person can manufacture a drug (including marijuana) without a registration issued by DEA, *see id.* § 822(a), and in that registration DEA can limit the “extent” to which any person is “authorized to . . . manufacture” marijuana under their registration, *id.* § 822(b). Section 823(e) provides yet another potential source of authority for imposing a manufacturing quota on a Schedule III drug, as DEA could conclude under section 823(e) that registrations to manufacture marijuana would be “inconsistent with the public interest” unless a quota consistent with Article 21 of the Single Convention was implemented to maintain “effective controls against diversion.” *Id.* § 823(e); *see also Oregon*, 546 U.S. at 260 (identifying similar language in section 823(a) as providing regulatory authority).⁹

⁹ We note that section 823(a) provides that the Attorney General shall register manufacturers of Schedule I and Schedule II drugs upon determining that “such registration is consistent with the public interest and *with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.*” (Emphasis added.) In *Licensing Marijuana Cultivation*, we emphasized section 823(a)’s invocation of international obligations in concluding that DEA could promulgate regulatory controls necessary to meet certain of the United States’ obligations under the Single Convention. *See* 42 Op. O.L.C. __, at *24. Although section 823(e) does not include a similar requirement to

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In concluding that the CSA provides numerous sources of authority that could be used to impose a manufacturing quota, we recognize that section 826 expressly requires manufacturing quotas for drugs in Schedules I and II.¹⁰ But that requirement should not be read as implicitly foreclosing the imposition of such quotas for drugs in Schedules III through V. As the D.C. Circuit has recognized, “a congressional mandate in one section and silence in another often suggests not a prohibition but simply a decision . . . to leave the question to agency discretion.” *Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam) (quotation marks omitted).

We therefore conclude that both the Single Convention and the CSA permit DEA to place marijuana in Schedule III while imposing additional controls, pursuant to the CSA’s regulatory authorities, to close a modest gap between the requirements of the Single Convention and the requirements that follow from placement on Schedule III.

V.

For the reasons set forth above, we conclude, first, that DEA’s current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by

consider international obligations, it does require the Attorney General to consider whether registration is “inconsistent with the public interest,” 21 U.S.C. § 823(e), and complying with the United States’ international obligations is plainly in the public interest. Against this backdrop, we do not read Congress’s silence with respect to international obligations in section 823(e) as precluding DEA from relying on that section to comply with international obligations. See *Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam).

¹⁰ Although the CSA refers to quotas on the “production” of drugs and the Single Convention to quotas on the “manufacture” of drugs, we understand the scope of these terms to largely overlap. The CSA defines “production” to include the “manufacture, planting, cultivation, growing, or harvesting of a controlled substance,” 21 U.S.C. § 802(22), and, in turn, defines “manufacture” to include the “production, preparation, propagation, compounding, or processing of a drug,” *id.* § 802(15). The Single Convention defines “manufacture” to mean “all processes . . . by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs,” Single Convention art. 1(1)(n), but excludes “the separation of . . . cannabis and cannabis resin from the plants from which they are obtained,” *id.* art. 1(1)(t).

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FDA and would not satisfy DEA's five-part test. Second, we conclude that HHS's overall CAMU recommendation is not binding on DEA and that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rule-making proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process. Finally, we conclude that neither the Single Convention nor the CSA requires marijuana to be placed into Schedule I or II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific restrictions that follow from a drug's placement on a particular schedule. As a result, DEA may satisfy the United States' Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA's regulatory authorities.

CHRISTOPHER C. FONZONE

Assistant Attorney General

Office of Legal Counsel

September 30, 2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

3040 East Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Subject: Notice of Appearance

Dear Sir:

Please take notice that Jane Appleyard Allen will appear in the matter of: notice of proposed rulemaking to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA.

(A) (State with particularity the interest of the person in the proceeding.).

RTI International (RTI) is an independent nonprofit research institute dedicated to improving the human condition. We address the world's most critical problems with science-based solutions. Clients rely on us to answer questions that demand an objective and multidisciplinary approach.

RTI has decades of experience in cannabis research. Our scientists are working to develop roadside tests for cannabis impairment, investigating therapeutic uses for cannabis compounds, studying the conversion of CBD to THC in certain foods, conducting cannabinoid dosing studies to better understand toxicology and impairment, documenting the accuracy of cannabis product labeling, developing recommendations for cannabis warning labels and high potency cannabis products, studying the effects of cannabis public education and prevention programs, studying the effects of cannabis legalization on law enforcement and drug markets, and documenting cannabis use in national surveillance surveys.

RTI conducts cannabis-related research for state departments of public health and federal agencies, including the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the U.S. Department of Justice, and the U.S. Drug Enforcement Administration (DEA).

As part of our work, RTI cannabis experts have identified gaps in the science that, if addressed, would lead to substantial advancements in therapeutics, public health, and public safety.[1] Our research also has yielded several important lessons that should be incorporated into any cannabis scheduling decision to promote equity, public health, and research access.

Ms. Allen, a recognized expert in this field, requests to speak to these issues at the hearing on behalf of RTI. We recognize that, if invited to do so, we will be one of many to speak at the hearing. Therefore, we have limited our remarks to those issues that directly relate to our specific research experience rather than providing more expansive remarks on the possible impacts of rescheduling.

- (B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

RTI is not ready to endorse any specific action in regard to the question of transferring marijuana from schedule I to schedule III of the Controlled Substances Act (CSA), as the impacts of any change could vary dramatically based on implementation. Rather than endorse a specific policy direction, **we wish to highlight several priorities that must be considered in any scenario to advance equity, support and protect public health and public safety, and promote excellence in research.** We urge the DEA and other federal agencies engaged in shaping national cannabis policy to prioritize these tenets in their work, including not only in the immediate scheduling decision, but the many decisions that will follow as policy is implemented.

Ensure that Federal Cannabis Policy Advances Equity

RTI recently conducted a study in partnership with the Parabola Center for Law and Policy to document U.S. adults' values and beliefs about national cannabis policy. The study showed that, when it comes to cannabis policy, survey respondents cared most about social equity (68 percent) and ending marijuana arrests (68 percent), followed by ensuring that people have access to cannabis (65 percent). One of the most important takeaways from this study is that respondents do not want the cannabis industry to be controlled by large corporations that have historically prioritized profit over consumer well-being and public health—specifically the pharmaceutical, alcohol, and tobacco industries.[2-6]

Ensure that Federal Cannabis Policy Supports and Protects Public Health and Public Safety

Over the past 12 years, nearly half of U.S. states, four territories, and the District of Columbia have developed and implemented adult use cannabis policies. In the absence of federal guidance, states have developed a wide variety of regulatory approaches, each with different impacts on public health and public safety. State agencies share information and resources but are not well positioned to conduct the policy evaluations needed to identify specific regulations that best support and protect public health and safety. An example is the varying state policies to address high potency cannabis.[7] Studies show a dramatic increase in cannabis product potency over the last several decades, and use of higher potency cannabis is associated with greater adverse health and safety outcomes.[7-9] Nevertheless, regulations that shape the availability and marketing of high potency products differ by state, likely resulting in different public health and safety outcomes.

Reports from the National Academies of Sciences, Engineering, and Medicine (NASEM) published in 2017 and 2024 call for a national cannabis research agenda [10, 11] to “address the many data gaps that need to be filled to improve a public health approach to cannabis policy.”[11] As part of this much-needed national research agenda, the federal government can promote excellence in research through policies that facilitate cannabis research on roadside tests of impairment, standards for cannabis testing labs, and better understanding the health and safety impacts of high potency cannabis.

Today, there is no nationwide standard for cannabis-impaired driving, and state-based standards can vary dramatically and frequently lack supporting scientific evidence. A key reason for the absence of a national standard is the lack of a reliable chemical test for cannabis impairment such as the blood alcohol concentration (BAC) or breath alcohol concentration (BrAC) tests for alcohol impairment.[12] Additional research is critical to developing an effective, field chemical test that can reliably determine impairment in drivers. The federal government can facilitate this area of research by funding studies on novel technologies and by broadening the scope of the research beyond cannabis, to include roadside tests of impairment from any cause.

Ensure that Federal Cannabis Policy Promotes Excellence in Research

High quality cannabis-related research is integral to policymaking and must not be impeded unintentionally by CSA regulation. Although the DEA sought to expand access to research cannabis in 2021, [13] research still faces undue barriers due to continued access issues. As a result, lab scientists are challenged in conducting research to better understand adverse health and safety outcomes related to high potency cannabis.[7] The federal government can facilitate important research on high potency products by evaluating and adjusting policies related to cannabis research samples, including by considering a schedule change or descheduling of cannabis.

In another example, recent news reports indicate that cannabis companies “shop around” for labs that will certify their products as suitable for sale, despite the presence of mold and other contaminants.[14] To protect consumer safety, the development of a national quality assurance program is of utmost importance to enforce lab standards. SAMHSA’s National Laboratory Certification Program (NLCP) is an appropriate model for this program.[15] The federal government can protect consumer safety by implementing a quality assurance program to certify cannabis testing labs.

In sum, if cannabis is transferred from schedule I to schedule III of the CSA, RTI urges federal agencies to conduct a careful evaluation of the impact of that change on equity, public health and safety, and the ability of the research community to conduct and communicate the cannabis research that is most needed in the United States today.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

RTI scientists do not at this time endorse any specific action in regard to rescheduling. Rather, we advocate for policy—and importantly, policy implementation—be shaped by evidence-based principles and values that are consistent with our mission as nonprofit research institute dedicated to improving the human condition. These values are to advance equity, to support and protect public health and public safety, and to promote excellence in research. We urge the DEA and other federal agencies engaged in shaping national cannabis policy to make policy decisions through the lens of these values. In doing so, they will also be making decisions that are consistent with the values of the American public.

RTI stands ready to contribute our expertise and decades of experience in cannabis research to this important discussion.

All notices to be sent pursuant to this appearance should be addressed to:

Jane Appleyard Allen
3040 East Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

Respectfully yours,
Jane Appleyard Allen

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[EXTERNAL] Request to Participate in DEA Hearing on Rescheduling of Marijuana

From Russell palmer <russ@russellpalmer.biz>

Date Mon 9/30/2024 1:19 AM

To NPRM <NPRM@dea.gov>

Dear Drug Enforcement Administration,

I am writing to formally express my interest in participating in the hearing scheduled for December 2, 2024, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act.

While I acknowledge the proposed rescheduling, I firmly believe that marijuana should be descheduled entirely. My interest in this proceeding stems from the following points:

1. The medical benefits of marijuana and its potential to improve the quality of life for many patients, especially those who are incarcerated and suffer from health issues exacerbated by their imprisonment. Rescheduling could inadvertently reinforce the stigmatization of marijuana as a political tool rather than recognizing its therapeutic properties.
2. The importance of acknowledging the long-standing impact of marijuana prohibition on marginalized communities, leading to mass incarceration and injustice. Descheduling marijuana would be a crucial step toward rectifying these historical wrongs and alleviating the burden on those who are currently imprisoned for marijuana-related offenses.
3. The economic and social benefits of removing all regulatory barriers related to marijuana, which would allow for better access and innovation in treatment, while also creating opportunities for those affected by the War on Drugs.
4. I believe plant medicine is a God-given right. Cannabis should be protected by 1st Amendment Rights. Not only is a whole community censored because of their medicinal usage and educational nature of their stance, social media and other media platforms censored the entire cannabis industry of folks. While the proof exists that the cannabinoids are like a key to our Endocannabinoid System, which proves the God-given nature of cannabis, but it shows the nature of the decision to FINALLY call cannabis medicine is convenience for DEA and refer it to the BIG Pharma who will mono crop and strip away ALL genetic values of the diversity of cannabinoid profiles associated with the many strains of cannabis. Cannabis is individualized medicine and the consistent use needed for cannabis therapeutic healing, requires for users to make decisions on their own needs, not a pharmaceutical system.

I appreciate the opportunity to participate in this important discussion.

Sincerely,

Russell Palmer

San Diego CA

CERTIFICATE OF SERVICE

I certify that this document was filed with the Court via the court's electronic filing system, on the 17th day of February, 2025, and an electronic copy was served on all counsel of record via the CM/ECF system on the same date. I further certify that I have mailed the foregoing document via first class mail, postage paid, to those parties or their counsel who are not registered through the CM/ECF system.

/s/Austin T. Brumbaugh

Austin T. Brumbaugh